

Investigation of Pre-washed Mixed Bagged Salad following an Outbreak of *Escherichia coli* O157:H7 in San Diego and Orange County

Date: October 6 – May 17, 2004

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Background/Epidemiology:

On October 6, 2003, the County of San Diego Health and Human Services Agency notified the California Department of Health Services (CDHS) of a cluster of five patients with *E. coli* O157:H7 infections who had all eaten food from one of two Pat and Oscar's restaurants in San Diego County. Because this restaurant chain has 20 restaurants in Southern California, CDHS sent an alert about the outbreak to all communicable disease control officers in the State.

A total of fifty-seven (57) cases with symptom onsets between September 16 and October 15, 2003 were identified. Forty-two (42) were laboratory-confirmed cases with isolates that had identical or nearly identical, pulsed field gel electrophoresis (PFGE) patterns. Fifteen (15) were probable cases with onset of unexplained bloody diarrhea or hemolytic uremic syndrome (HUS) 1-9 days following food consumption at a Pat and Oscar's (PO) restaurant. Fifty-six (56) patients resided in California, in the counties of: San Diego (n=37), Orange (n=8), Riverside (n=6), Los Angeles (n=4), and San Bernardino (n=1). One patient resided in Florida. The exposure dates ranged from September 27 through October 6, 2003. The onset dates ranged from September 30 through October 12, 2003. Three patients had HUS, 15 patients were hospitalized for 1-9 days and there were no deaths.

Fifty (50) laboratory-confirmed or probable cases, that were not considered secondary cases, had eaten at a PO restaurant within 9 days of symptom onset. Thirty-six (36) cases had eaten at one of five restaurants in San Diego County, 12 had eaten at one of three restaurants in Orange County, and two ate at one restaurant in Riverside County.

To determine a possible food vehicle, a case-control study was conducted with 50 cases and 52 controls. Study participants were asked about their consumption of each food item on the PO

menu. Case-patients were more likely than controls to eat any fresh salad (98% vs. 71%, $p<0.001$). Of the 48 patients who ate salad and could recall the specific salad they consumed, 36 ate a Greek salad, 6 patients ate a Lemon Chicken salad, 3 patients ate a Cobb salad, and 3 ate an antipasto salad. All four of these salads were prepared with the same base salad mix of 70% iceberg lettuce and 30% romaine lettuce. Case-patients were more likely than controls to consume the salad mix (98% vs. 65%, $p<0.001$).

An additional two laboratory-confirmed patients (with matching PFGE patterns) did not eat at PO restaurants but did eat salad in the week prior to their onsets, at one of two different schools in San Diego County between September 30 and October 8, 2003. Another patient who ate at PO, but who did not eat a salad at the restaurant had eaten salad served by a third school in San Diego County between September 24, 2003, and October 1, 2003.

CDHS-Division of Communicable Disease Control (DCDC) provided final results of this epidemiological investigation to California Department of Health Services Food and Drug Branch (CDHS-FDB) on May 12, 2004. For additional information on the epidemiological investigation, contact DCDC.

Summary:

On October 7, 2003, CDHS-FDB staff and CDHS-Emergency Response (ERU) staff began environmental and traceback investigations of the prepackaged 70/30 lettuce mix implicated in an outbreak of *E. coli* O157:H7 illnesses in Southern California (Attachment 1). Traceback and environmental investigations implicated a “70/30 lettuce mix” and a “4-way-bite-size” lettuce mix manufactured by Gold Coast Produce (GCP), an unregistered food processor, in Oxnard, California. Iceberg lettuce and romaine were the only common ingredients in the 70/30 lettuce mix and the 4-way-bite-size lettuce mix. GCP agreed to voluntarily cease operations and began a voluntary recall of iceberg lettuce and romaine products on October 8, 2003. Numerous violations of Title 21, Code of Federal Regulations, Part 110, Current Good Manufacturing Practice in Manufacturing, Packaging, or Holding Human Food (GMPs) were documented at GCP. The two implicated salad mixes were sold to three distributors: Family Tree Produce (FTP) in Anaheim, California; Produce Available in Oxnard, California; and The Berry Man in Santa Barbara, California. FTP resold the implicated 70/30 lettuce mix to PO Restaurants and the 4-way-bite-size mix to school districts. Produce Available and The Berry Man resold the 4-way-bite-size lettuce mix to various retail and food service accounts in Southern California including school districts, restaurants, and health care facilities. Distribution information was provided to local jurisdictions. The farm traceback identified 29 fields from 19 ranches that supplied iceberg lettuce and romaine during the time frame of concern. Chinn Ranch 3, one of the 19 ranches, had been identified in two previous *E. coli* outbreaks (July 2002, - October 2003) of romaine and spinach respectively. Additional investigations of Chinn Ranch and the surrounding environment are currently in progress by CDHS-FDB and county agencies.

Traceback Investigations:

Pat and Oscar's - Traceback Investigation

Contacts:

Melissa Master-Holder, Director of Training
10679 Westview Parkway, San Diego, California 92126
(858) 695-8500 ext 3531

Jeff Dingwall, General Manager – Downtown San Diego, 501 First Street, San Diego, California 92101; 4510 Executive Drive, Suite 225, San Diego, California 92121
(619) 515-0877

On October 7, 2003 Dr. Thomas, Dina Ellorin (Senior Environmental Health Specialist, Department of Environmental Health, Food & Housing Division, County of San Diego), and Investigator Thanh Andrews, United States Food and Drug Administration (FDA-Los Angeles District) met with PO representatives at the Downtown PO restaurant (501 First Avenue, San Diego, California 92101) to obtain traceback information. Ms. Master-Holder stated, and invoices confirmed, that all produce ingredients and salad dressings used to make the salads were supplied by FTP. The 70/30 lettuce mix was shipped directly by FTP to the individual PO restaurants in five-pound sealed, plastic bags. ERU staff noted three types of bagged salad products in the walk-in cooler at the Downtown PO restaurant. The first mix was 70% iceberg lettuce and 30% romaine (70/30 lettuce mix). GCP supplied the 70/30 lettuce mix to PO through FTP. The other two bagged salads were pre-washed spinach and chopped romaine. River Ranch (RR) in Salinas, California supplied both of these products (spinach and chopped romaine) to PO restaurants through FTP (Attachment 2). PO used only the 70/30 lettuce mix to prepare the salads implicated in this outbreak.

During the visit, Ms. Master-Holder provided the ingredient list for each salad (Attachment 16). PO also provided copies of invoices from FTP for all produce delivered to PO restaurants from September 15 to October 7, 2003 (Attachment 3). Some of these invoices note refusal of lettuce product due to poor quality.

Family Tree Produce - Traceback Investigation

Contacts:

Fidel Guzman, President
Bob Kaspereen, General Manager
Bill Grigsby, MIS Director
5510 E. La Palma Avenue, Anaheim, California 92087
(714) 696-3037

On October 7, 2003, Investigator Myers and Dr. Thomas visited FTP to obtain documentation linking transfer of product from FTP to PO restaurants. Mr. Guzman informed ERU staff that FTP is a produce distribution center and does not process, package, or repack any lettuce products. Mr. Guzman confirmed the 70/30 lettuce mix shipped to PO restaurants was processed and supplied by GCP. The 70/30 lettuce mix was a special order product that was processed by GCP specifically for PO restaurants. However, Baja Sonora Grill and Baja Sonora, both of Long

Beach, California, received nine cases of 70/30 lettuce mix during the time period of September 15 through October 6, 2003 (Attachment 4). No cases were associated with these two restaurants.

Mr. Guzman confirmed that the 70/30 lettuce mix was a specialty lettuce mix made of 70% iceberg lettuce and 30% romaine and packaged in a five-pound clear sealed plastic bag. No labeling or markings on the bags identified the product or the supplier. The bags were shipped in a box (four bags per box) labeled “Gold Coast Produce, Port Hueneme, California” (Attachment 5A). The bags had a small paper sticker that contained a four-digit lot number and production date. FTP provided invoices for deliveries of 70/30 lettuce mix to PO restaurants for September 15 through October 6, 2003 (Attachment 3). FTP also provided documentation showing receipt of product from GCP for September 15 through October 6, 2003 (Attachment 6). This time frame accounted for the distribution of salads from GCP through FTP to PO restaurants during the outbreak time frame.

FTP also sold two different types of lettuce mixes, containing carrots and red cabbage, to several school districts. Both of these products contained a romaine-iceberg mix with vegetables (carrots and red cabbage) added for coloring. The first salad mix, referred to as “4-way-bite-size-separated”, was produced by GCP. The 4-way-bite-size-separated salad was a five-pound bag of the 70/30 lettuce mix that contained a separate cellophane bag of carrots and another bag of red cabbage within the five-pound bag. This was a special order product for schools that preferred the colored vegetables to be packaged separately from the lettuce mix. As with the 70/30 lettuce mix, the individual plastic bags were not labeled or identified. However, this product was identified on FTP invoices as “Mix Sld 4WY separated” and the wording “Send Gold Coast Mix Salad Only” was printed at the bottom of the FTP invoices. The second salad mix was also a product sold to schools and was referred to as “4-way-bite-size”. FTP purchased this product from River Ranch (RR) in Salinas, California. This salad mix was made of 80% iceberg lettuce and 20% romaine lettuce mix with the colored vegetables added directly into the lettuce mix and packaged in five-pound bags.

School customers of FTP ordered either the “4-way-bite-size separated” or the “4-way-bite-size” lettuce mix. However, FTP drivers would substitute the GCP “4-way-bite-size-separate” salad for non-GCP “4-way-bite-size” salad when inventory was insufficient. The FTP driver or persons at the schools receiving the product typically did not note the substitution on the invoices. Therefore, ERU staff were unable to determine exactly which schools received a lettuce mix processed by GCP. FTP did provide a “best guess” of the school districts that may have received the product, however, no written evidence was available.

ERU staff obtained a complete list of customers that received any lettuce products from FTP (Attachment 7). FTP also provided invoices showing the 4-way-bite-size-separated mix movement from GCP to schools and school districts (Attachment 8).

On October 8, 2003, Dr. Mary Palumbo (CDHS-FDB) forwarded a FTP distribution list to San Diego County Environmental Health (Ms. Ellorin) and Orange County Environmental Health (Ms. Martinez). The list included schools, Pat and Oscar's locations, and other Points of Service

(POS) that received this product as verified by invoices and information provided by FTP. Dr. Palumbo also notified Environmental Health in the City of Long Beach.

On October 9, 2003, Dr. Palumbo received an e-mail from Robert Venter (San Diego County Environmental Health) reporting that he had spoken with David O’Riordan from Sodexho (a food facility management service) and learned that additional school districts received produce from FTP through Sodexho. These districts may have received GCP lettuce as a back up to the blended product that they normally receive. Dr. Thomas spoke with Sodexho Marriott Quality Assurance Director Kirt Mehta, who confirmed that Sodexho manages food service operations for certain Southern California schools and purchases produce from FTP for these operations. Dr. Thomas confirmed that the additional school districts could have received the product if the drivers used GCP lettuce as a substitute for RR products. However, this information could not be documented with invoices from the schools or FTP.

On October 16, 2003, Dr. Palumbo informed Mr. Venter that ERU staff could not confirm whether schools did or did not receive GCP until further information was received from the firm. During a conference call held on October 17, 2003, San Diego County Communicable Disease (Ms. Hopkins) requested that an additional distribution list be created to include all school districts that received any processed lettuce product from FTP. Dr. Palumbo created a list based on the FTP customer list. This list was then sent to CDHS-DCDC on October 17, 2003. On October 20, 2003 DCDC forwarded the information to all counties involved.

Gold Coast Produce (GCP) - Traceback Investigation

Contacts:

Jaime Montiel and Robert Montiel, Owners
4444 Naval Air Road, Oxnard, California 93033
(805) 701-8495

On October 8, 2003, Investigator Myers interviewed Mr. Jaime Montiel and Mr. Robert Montiel, partners of GCP. GCP is a corporation filed under the name of Ventura Veg. Mr. Macario Montiel, the father of Jaime and Robert Montiel is the corporate president. GCP’s customer sales list identified FTP as the only account receiving 70/30 lettuce mix (Attachment 9). Invoices, from September 15 through October 6, 2003, showed shipments of the 70/30 lettuce mix from GCP to FTP (Attachment 10). These dates were chosen to be inclusive of the *E. coli* O157:H7 incubation period, the case-patient exposure dates, and the time from harvest to delivery. September 15, 2003, was considered to be the earliest date that a product could have been processed by GCP and received at PO restaurants to coincide with the earliest reported PO exposure date of September 27, 2003. October 6, 2003, represents the last date of delivery for any potentially contaminated product into the PO restaurants from GCP for consumption by the case with the latest reported PO exposure date of October 7, 2003. All GCP products delivered to FTP and PO restaurants after October 6, 2003, were removed from commerce and were not sold to the public.

Invoices and bills of lading were obtained from GCP for the lettuce used to make the 70/30 lettuce mix. September 15, 2003, was considered to be the earliest date that lettuce could have

been shipped from the grower, processed by GCP, and received at PO restaurants to coincide with the first PO exposure date of September 27, 2003. October 6, 2003, represents the last date of delivery that could have been received by a PO restaurant before the last PO exposure date of October 7, 2003.

GCP received romaine and iceberg lettuce implicated in this outbreak from Diamond Produce (DP) of Salinas, California. DP is a grower/shipper and therefore contracts with farmers to grow produce. DP took ownership of the crop at maturity and was responsible for harvesting, boxing, cooling, and cold storing the lettuce. GCP used a common carrier to transport the lettuce from cold storage to their Oxnard facility. GCP received an average of two lettuce shipments per week from DP. Romaine was received in boxes and iceberg was received in 900-pound plastic-lined bins. DP supplied GCP with approximately 30 bins of iceberg lettuce and approximately 683 mini-bins (40 - 50 pound-boxes) of romaine per week. GCP received iceberg lettuce shipped as cored or un-cored in bins directly from DP. Romaine was shipped to GCP as cored or un-cored in 40 or 50 pound plastic-lined boxes. All DP romaine and iceberg cored lettuce was cored in the field during harvest. DP growers did not grow the romaine provided to GCP, rather the romaine was brokered through DP for shipment to GCP.

Diamond Produce (DP) - Traceback Investigation

Contacts:

Frank Pinney, General Manager
Frank Ballesteros, Sales Manager
P.O. Box 6970 Salinas, California 93912
(831) 758-3758

On October 20, 2004, Investigator Myers and Dr. Thomas visited DP to continue the traceback investigation. Mr. Ballesteros informed ERU staff that DP is a produce grower/shipper. Each season, DP contracts with several growers throughout the Salinas Valley to grow iceberg lettuce. Rather than contract with growers to grow romaine, DP buys romaine from a variety of growers once the crop is harvest ready. DP purchased romaine lettuce, used in the 70/30 lettuce mix implicated in this outbreak, from RR, Paul's Pak, and The Pismo Oceano Vegetable Exchange (POVE). DP provided invoices, daily shipping reports, and bills of lading documenting harvest and shipment of iceberg lettuce and romaine to GCP from September 2 to October 7, 2003 (Attachment 11A-C).

DP used their equipment and harvest crews at their contract growers' fields for the iceberg lettuce implicated in this investigation. Lettuce was transported in DP trucks to 3-D Cooling in Salinas, California. Romaine crops were either harvested by a DP crew, the grower's crew, or a contract crew.

DP provided a list of farms that grew the implicated iceberg lettuce harvested from September 2 to October 2, 2003 (Attachment 12). Mr. Ballesteros identified seven growers and 16 fields that supplied iceberg lettuce during this time frame. Field identifications were recorded on the bills of lading. Mr. Ballesteros also identified 13 fields that supplied romaine lettuce for these harvest

dates. The bills of lading and daily shipping reports can be used to identify the field and grower for romaine lettuce purchased by DP (Attachment 11C).

DP supplied the ERU staff with iceberg lettuce harvest dates, field identification, and lot numbers used to identify fields that were harvested during the time period of interest. Iceberg lettuce, represented on the bills of lading, is matched to the grower by the identification number (ID#) listed on Attachment 12. This ID# is hand-written underneath “description of articles shipped” on the bills of lading and can be cross-referenced to Attachment 12 to identify the grower and growing field.

Paul’s Pak – Traceback Investigation

Contact:

Sal Tarantino, Owner

975 Alisal Street, Salinas, California 93920

(831) 757-6288

Paul’s Pak contracted one section of a romaine field sold directly to DP. DP harvested, packed, and transported the romaine lettuce from Paul’s Pak to GCP. Because Paul’s Pak was not directly involved in the growing or harvesting of the product, no other information on Paul’s Pak is provided in the report. However, information on the grower and field that supplied this romaine is provided under the DP environmental investigation (see Franscioni Brothers, Barrett Ranch).

River Ranch (RR) – Traceback Investigation

Contact:

Anne Pauly, Quality Assurance

1085 Abbott Street Salinas, California 93901

(831) 770-6304

On October 23, 2003, Dr. Thomas visited River Ranch (RR) as part of the traceback investigation. Ms. Pauly informed Dr. Thomas that four romaine fields were harvested in September 2003, and sold under contract to DP. The romaine lettuce was harvested by a RR harvest crew, packed into DP boxes, cooled by 3-D Cooling, and shipped to GCP. RR provided ERU with bills of lading (referred to as Outside Sales Invoices Request) that documented the sale of romaine lettuce to DP (Attachment 13). The growers and fields where the implicated product was grown and harvested are noted on Attachment 13. Ms. Pauly reviewed the information with ERU staff and made arrangements for farm visits.

Pismo Oceano Vegetable Exchange (POVE) – Traceback Investigation

Contact:

Dan Sutton, Plant Manager
P.O. Box 368, Oceano, California 93445
(805) 473-4930

DP purchased romaine lettuce for direct shipment of product to GCP through POVE. Four POVE romaine fields were harvested during the outbreak time frame. POVE was responsible for growing, harvesting, cooling, and shipping the romaine. All shipments of romaine to GCP were made within two days of the harvest date. Invoices and bills of lading were obtained for romaine lettuce shipped from September 1 through October 3, 2003 (Attachment 14).

Environmental Investigations

Pat and Oscar's (PO) - Environmental Investigation

On October 7, 2003, Dr. Thomas, Ms. Ellorin, and Investigator Andrews met with PO representatives at the Downtown PO Restaurant to observe salad preparation practices. San Diego and Orange County Environmental Health Departments conducted inspections of PO restaurants where illnesses occurred (Attachment 15).

PO used three varieties of processed lettuce or spinach to prepare Caesar, Spinach, Greek, Lemon Chicken, and Cobb salads that were sold in their restaurants. Attachment 16 identifies the ingredients and preparation methods for these salads. The spinach salad was made using pre-washed processed bagged spinach from RR (Attachment 17A). Other salads (Greek, Lemon Chicken, Cobb) were all prepared using the GCP lettuce base of pre-washed, processed 70/30 lettuce mix.

The 70/30 lettuce mix was delivered to PO restaurants in sealed five-pound bags, packaged in GCP boxes (4 bags per box), directly from FTP (Attachment 5A). FTP typically delivered the lettuce products in the mornings before PO restaurants were open to the public. According to Ms. Master-Holder, the 70/30 lettuce mix bags were stored on shelving off the floor in the walk-in cooler at each PO restaurant along with other produce items. On the day of the visit at the Downtown San Diego location, all produce and ready-to-eat products were stored in the walk-in cooler. Raw meat and dairy products were in the same cooler, but were stored separately from the fresh produce.

The Greek, Lemon Chicken, and Cobb lettuce bases were prepared in the morning by employees on the prep station using the 70/30 lettuce mix (Attachment 5B). Mr. Dingwall explained that all salad preparation occurred on a prep station that is used only for making salads and other cooked ready-to-eat products. According to Ms. Master-Holder, no raw meat or poultry ingredients are handled on the prep station. Investigators observed that an employee wearing plastic gloves opened a 70/30 lettuce mix bag at the prep station to begin making the salads. Next, the employee placed the salad mix in individual serving bowls and then into a refrigeration unit located under the prep station (Attachment 17B).

PO's policy was to have salads individually made by employees throughout the day by adding dressing and ingredients to the 70/30 lettuce mix as a customer places an order. During the

observation of the lettuce preparation, some of the prewashed bagged spinach, used by an employee to make a spinach salad, had soil on the leaves. The employee removed the soil by wiping the leaves with a towel. None of the base lettuce products were washed or rinsed while the investigators were present.

The last shipment of 70/30 lettuce mix delivered to PO from FTP was on October 7, 2003. David Hill, Food and Beverage Manager at PO, was notified by Dr. Jeff Farrar, Section Chief, Food Safety Section, CDHS-FDB, on October 7 to stop selling all lettuce products processed by GCP. By 4:00 PM on October 7, 2003, PO restaurants discontinued serving all salads. Mr. Hill then notified PO restaurants to discard all 70/30 lettuce mix. FTP issued credit to all PO restaurants that had returned or discarded the recalled product (Attachment 18).

Family Tree Produce (FTP) - Environmental Investigation

Contacts:

Bob Kaspereen, General Manager
Bill Grigsby, MIS Director
5510 E. La Palma Avenue, Anaheim, California 92087
(714) 696-3037

Investigator Myers and Dr. Thomas visited FTP on October 7, 2003, to conduct an environmental investigation. Dr. Thomas revisited the firm on November 19, 2003. Mr. Grigsby and Mr. Roberto Zavala (distribution manager) were present during the environmental investigations. FTP is a warehouse and distribution center. FTP does not package, process, or repackage any produce items. FTP distributes produce items and some dairy products to Southern California area retail firms and school districts.

FTP received the 70/30 lettuce mix directly from GCP. Monday through Friday, FTP used refrigerated trucks to transport 70/30 lettuce mix from GCP in Oxnard to the FTP distribution center in Anaheim. FTP did not receive product from GCP on Saturdays. On Sundays, GCP delivered product to the FTP distribution center in refrigerated trucks. FTP records show that daily deliveries of 70/30 lettuce mix from GCP varied between 25 - 278 cases during the time period of interest (Attachment 19). When the produce arrived at the FTP distribution center, it was unloaded into a refrigerated docking area until being transferred to the cold storage area. Lettuce and processed lettuce products were held in the cold storage area until the product was ordered and shipped to the retail customer. All products were placed "first-in-first-out" so that the older produce was delivered to customers first. The GCP 4 way-bite-size and the 70/30 lettuce mix were stored in the cold storage area until they were distributed to schools and PO restaurants.

The cold storage area was directly adjacent to the staging area and was separated by a plastic curtain (Attachment 20A). It was noted that no items were stored directly on the floor, but off the ground on shelving or pallets. During the investigation, three temperature gauges were noted in the cold storage area. One temperature gauge, located in the middle of the room, mounted to a wall, registered 37°F (Attachment 20B). The ambient temperature was recorded at 39°F by the investigators using CDHS-FDB equipment (Atkins Temptec, Model 330). ERU staff measured

the temperature to be 36°F in a box of head lettuce that was located in the cold storage area. The other two temperature gauges were located near the doorway that separates the staging area from cold storage. Those temperature gauges measured 39°F at the time of the investigation. According to Mr. Grigsby, temperatures are monitored in the room and recorded in the “storage temperature report” log twice a day (Attachment 21).

FTP transported 70/30 lettuce mix and 4-way-bite-size-separated in their refrigerated trucks from the distribution center to the retail POs and schools daily. The process for delivering a product from the distribution center to the retail POS began at approximately 6 PM in the evening. At that time, orders for the next day’s delivery were pulled from the cold storage and placed into the refrigerated staging area. All orders were placed into the staging area on pallets until the produce was ready to be loaded into the trucks. ERU staff measured the temperature in the staging room at 41.6°F.

At approximately 8 PM, the delivery trucks were started and left to idle with the truck refrigeration unit cooling. According to Mr. Zavala, the trucks were left idling with the refrigeration units operating until the temperature inside the truck cargo area reached 34°F. Once the temperature inside the truck reached 34°F, the trucks were backed into the loading docks. A temperature log was kept for each truck. The logs included the temperature when the refrigeration unit was first started and when the temperature reached 34°F (Attachment 22). A plastic liner at the loading docks created a barrier between the outside of the building and the staging area.

After loading, the drivers would leave the docks either for the delivery schedule or back the truck into the parking lot to idle until the delivery was ready to be made. Each truck served several accounts. A remote temperature probe located inside the truck’s cab monitored the refrigeration units on all trucks. A second temperature gauge was located in the cargo hold of the truck.

Gold Coast Produce (GCP) - Environmental Investigation

Contacts:

Jaime Montiel and Robert Montiel, Owners
4444 Naval Air Road, Oxnard, California 93033
(805) 701-8495

On October 8, 2003, FDB Investigators Carol Myers and Angela Powe met Jaime and Robert Montiel, at the firm’s facility on 4444 Naval Air Road, Oxnard, California. FDB Investigator Powe conducted a GMP inspection. Sarah Hassas, FDA Los Angeles District, was also present and conducted an inspection of the facility. Investigator Powe’s Investigation Report, dated October 8 and 9, 2003, gives a general description of the GCP facility (Attachment 23). A Report of Observations (RO), dated October 8 and 9, 2003, (Attachment 24), lists alleged GMP violations observed at GCP. Jaime Montiel acknowledged the RO. Sarah Hassas also left an inspection report with alleged violations (Attachment 25). Investigator Myers’ focus was on determining the processing procedures for the 70/30 lettuce mix, evaluating the sanitary conditions under which the mix was handled, produced, and shipped, and obtaining traceback documentation. At the time of the investigation, GCP had been in business as a processor for

approximately six months and was not registered with the CDHS as a food processor as required by California law (Attachment 24, Item #1).

GCP leases their facility from San Miguel Produce, Inc (SMP). SMP operates a processing plant in the same building where space is leased to GCP. GCP leased a large refrigerated room used for processing, packaging, and storage. GCP also leased office space in a separate building. GCP received and shipped product from a dock also used by SMP. All other business activities between GCP and SMP were separate. The entire facility is supplied with municipal water.

GCP processes a variety of produce items such as salad mixes (including iceberg lettuce and romaine), fruit cups, and chopped vegetables. Using common carriers, GCP received approximately two lettuce shipments (30-40 bins of iceberg lettuce and 250-450 boxes of romaine) weekly from DP in refrigerated trucks. Lettuce is received at GCP on the same day it is shipped from DP. The 70/30 lettuce mix implicated in the outbreak was generally shipped from GCP to FTP within four days after the raw ingredients were received at GCP.

Raw products were unloaded on the dock and were immediately transferred to GCP's refrigerated facility. The refrigerated facility lies between two of SMP's rooms. SMP's cold storage room and receiving dock are on one side, with SMP's production room on the other side (Attachment 26). The GCP refrigerated facility is open with no walls separating any of the processing, storage, and packaging activities. Plastic strips cover the entrances to the SMP's rooms. Refrigeration for the GCP room was controlled by a separate thermostat from the refrigerated SMP's rooms on either side.

At the loading dock, fork lifts unloaded raw ingredients from refrigerated trucks. The forklifts passed through SMP's cold storage room on their way to the GCP area of the building. The majority of raw ingredients were stored in the back of the facility that was separated from the production area by a forklift runway (Attachments 27A-B). On the day of the visit, the runway section of the cement floor contained a layer of soil covered with water (Attachments 27B, 28A-B, & Attachment 24 Item #10). The forklift runway was also used by SMP to transfer raw ingredients from their cold storage room to their processing room and to transfer product from the processing room to the loading dock. The majority of raw ingredients, stored at the time of the investigation, were lettuce, peppers, oranges, onions, carrots, jicama, celery, green onions, and cabbage. All raw ingredients were stored in cardboard boxes or plastic bins on wooden pallets. Pallets of raw ingredients were stored on the floor and on metal shelving.

Processing was completed on two main lines and one cutting board area in the facility. Line #1 was used to process lettuce and Line #2 was used to process diced and sliced vegetables. The cutting table was used to cut oranges and vegetables for individual serving cups, prepare four-ounce salad cups, and vegetables for dicing on Line #2. GCP had forty employees working two shifts. The first shift was from 0400 hours to 1230 hours and the second shift was from 1300 hours to 2100 hours. A two-person crew cleaned the facility after the last shift.

Processing of the 70/30 lettuce mix began by transporting pallets of lettuce to the hopper at the end of Line #1 (Attachment 29A). The firm processed romaine and iceberg lettuce on Line #1 simultaneously. The product was either dumped by forklift or placed onto the stainless steel

hopper of Line #1. Employees, on either side of the belt, picked up heads of lettuce and trimmed and/or cored the lettuce using a knife. GCP received most iceberg lettuce cored and most of the romaine un-cored. During the inspection, the trimming board was observed to be heavily stained and gouged (Attachments 29B & 24 Items #7, #8).

Once cored and trimmed, the lettuce was placed onto the upper level conveyor belt of Line #1. Next, the lettuce was sliced in an automatic slicer and transferred by elevator to a swirl bath (flume #1) consisting of a metal drum with water jets (Attachment 30A). After the swirl bath rinse, the lettuce was dumped onto a perforated, dewatering belt. The swirl bath wash water was recirculated from a reservoir (reservoir #1) below the drum to the spray jets of the swirl bath (Attachment 30B). On October 8, 2003, ERU staff measured the water quality of reservoir #1. Using an ORP Tester (Double Junction Model/356050-02) the water in this reservoir had an ORP of 396 mV. Next, the lettuce moved into a flume (flume #2), out onto a vibrating belt, and fell into plastic food-grade spin buckets (Attachment 30C). Flume #2 water, tested with the same ORP meter, had an ORP of 479 mV (Attachment 30D). The buckets of washed lettuce were transferred to the spinner where additional water was removed. In the final step, the buckets of spun lettuce were dumped onto a stainless steel table where employees hand-filled, weighed, and sealed bags of salad mix. Red cabbage was being bagged on the day of the inspection (Attachment 31A-B).

Mr. R. Montiel stated that two workers spent approximately one hour per day spraying equipment, which was used primarily to hold raw ingredients (large plastic buckets and plastic trays) with a solution of sodium hypochlorite (12.5% sodium hypochlorite) and water. There were no SOPs for the mixing of this chlorine solution and the solution was not tested for chlorine levels once mixed. ERU staff recorded an ORP value of 830 mV for the spray solution. This chlorine solution was hand-pumped through an end-mounted nozzle (Attachment 32A). The sanitation spray occurred during processing hours and did not include processing lines. Mr. Montiel informed ERU staff that Line #1 is not cleaned or sanitized throughout the day as different raw ingredients were processed.

Item #9 on the RO dated October 8 and 9, 2003, cites the condition of unsanitary plastic product buckets used to transport processed ingredients to the packaging table (Attachment 32B). The large product buckets were placed on roller carts, which prevented them from touching the floor, however, plastic product buckets were observed stacked on top of each other at the time of this investigation (Attachment 33A-B).

The 70/30 lettuce mix was hand-packaged in five-pound clear plastic bags and vacuum sealed. Immediately after sealing, the bags were placed into a Gold Coast labeled cardboard box (four bags per box). The boxes were stored on pallets until transported by forklift to the loading dock. On October 8, 2003, FDA investigative staff collected 20 heads each of romaine and cored iceberg lettuce. The samples were submitted to FDA-Irvine Laboratory for *E. coli* 0157:H7 testing. All samples were negative for *E. coli* 0157:H7 (Attachment 34).

The firm did not have a Hazard Analysis Critical Control Point (HACCP) program. The firm did not participate in a third party audit program nor did it conduct environmental testing to verify cleaning and sanitation methods (Attachment 24 Items #2, #3).

All bags of salad mixes processed at GCP were identified by a small (approximately ½ inch by ½ inch) sticker with a production date and a lot code (Attachment 5A). GCP staff relayed that the shelf life for 70/30 lettuce mix produced by GCP was nine days. Adding nine days to the stamped production date on the packaged product would yield the expiration date. The lot code was a four digit purchase order number and could be traced to the supplier and the invoice for the product. All salad mixes were placed into a clear plastic bag with no lettering or distinguishing writing of any kind on the package other than the sticker previously described. The bagged lettuce was packaged in a cardboard box.

Employees were observed wearing aprons, latex gloves, sleeve protectors, and hair coverings while working in the processing area. Before leaving the facility, employees hung their gloves, sleeve protectors, and aprons on a wall hook. Upon returning to the processing area, employees were observed putting on the previously used gloves rather than obtaining new gloves.

As noted on the RO item #4, workers moved from one process and raw ingredient to another without sanitizing or cleaning their gloves or utensils (Attachment 24). An iodine hand dip was located on the wall of the west entry, however the levels of iodine and the maintenance of the dip were not monitored or documented (Attachment 35A). R. Montiel did not know the last time the iodine dip had been serviced (Attachment 24 Items #4, #6). At no time during the investigation did ERU staff observe a worker using the hand dip. As noted on the RO dated October 8 and 9, 2003, handwashing facilities were inadequate (Attachment 24 Item #6 & Attachment 35B).

Although there was more than one entry into the production area, only one foot dip was available to the employees. This foot dip was found to contain less than 1/4 inch of solution (Attachment 36A-B). Mr. R. Montiel did not have any documentation for the concentration of iodine in the foot dip or SOPs for properly maintaining the foot dip. The firm did not have an adequately trained supervisor to monitor personnel and sanitation procedures (Attachment 24 Item #2).

The FDB Investigation Report dated October 8 - 10, 2003, reported that Mr. J. Montiel stated employees attend food safety training quarterly (Attachment 23). Mr. J. Montiel stated that the employees sign and date a paper listing the training topics covered, which is placed into the employees' personal folders. Inspection of the employees' personal folders did not reveal these signed documents (Attachment 23). The firm monitors and records room temperature, some finished product temperatures, pH, and free chlorine for Line #1 and Line #2 (Attachment 37). Temperatures for the processing and storage areas were recorded within a range of 36-38°F. Mr. J. Montiel stated that the night cleaning crew rinsed off all debris from the equipment in the plant and then sanitized the equipment with a foaming agent. Mr. Montiel stated that rinsing and hosing the equipment was the firm's general practice for cleaning. There was no mention of scrubbing any of the equipment with brushes or other abrasives. The firm did not keep records of these activities or written Sanitation Standard Operating Procedures (SSOP). The firm did not have any documentation describing procedures for mixing sanitizing or cleaning agents in any areas of the plant. Mr. J. Montiel stated that a weekend crew scrubs and cleans the equipment and plant. The firm did not keep records or written SSOP for these weekend cleanings. Mr. J. Montiel stated that once a week a sanitizer cleaner is injected into the lines. Invoices

documenting the purchase and type of sanitizers were requested, however, the firm did not supply these papers. Mr. J. Montiel stated that these weekly cleanings alternate a chlorinator cleaner one week and an acid the next week. The firm kept no records or written SSOP of these cleanings.

Records were requested by ERU staff to document the purchase of sanitizers. Mr. J. Montiel supplied two Material Safety Data Sheets (MSDS). One MSDS dated January 10, 1999, was for sodium hypochlorite 7-15% (Attachment 38). The other MSDS dated April 9, 1986, was for a proprietary compound supplied by West Coast Water Services, Inc., Oxnard, California (Attachment 39). Mr. Greg Hummer of West Coast Water Services, Inc., identified this compound as a descaler used in refrigeration systems. ERU staff observed a large plastic tank of "Foam Chlor", liquid sodium hypochlorite (12.5%) outside on the west side of the building shared by GCP and SMP. Documents were not supplied by GCP to show ownership of this product.

On October 8, 2003, FDA staff observed the slicer blades on the automatic lettuce slicer to be unsanitary (Attachment 25 Item #6B). Mr. J. Montiel stated that the water was usually changed in the reservoirs of Line #1 at lunch and at the beginning of each shift. Mr. J. Montiel stated that once a week either a chlorine or acid sanitizer was run through Line #1 and Line #2. The firm did not provide documentation for the purchase of sanitizers and could not provide SOP's for the use of these compounds.

Mr. R. Montiel stated that the knives used to core and trim lettuce, slice oranges, cut jicama, onions, and other vegetables are cleaned daily with a foaming cleaner. The firm could not produce records to document these cleanings. The workers do not clean or sanitize the knives throughout the day as they move from one product to another. Knives were not properly cleaned as noted on the RO dated October 8 and 9, 2003 (Attachment 24 Item #8).

Mr. R. Montiel stated that the table used for slicing oranges and vegetables is cleaned daily with a sanitizing solution made from 12.5% calcium hypochlorite granules and water. The concentration of this solution was not measured, and there were no SSOPs for this procedure. The table was observed to be stained and with gouges on the surface (Attachment 40A). ERU staff observed dirt and onions on this table during the investigation (Attachment 40B).

Mr. R. Montiel stated that a worker measured free chlorine levels and pH from the flumes of Line #1 and Line #2 every three to five minutes and recorded this data once an hour (Attachment 37). ERU staff observed a worker taking these measurements. GCP's target level for free chlorine was 1.5 – 3 PPM and 7.0 for pH. Liquid 12.5% sodium hypochlorite was manually added to adjust the chlorine levels and citric acid was added to control the pH. Plastic jugs, identified by Mr. R. Montiel as containing sodium hypochlorite and citric acid, were unlabeled (Attachment 41). When the level of free chlorine measured below 1.5 PPM in either flume, a worker poured a small unmeasured amount of sodium hypochlorite into the flume. The free chlorine was not measured immediately after the addition of sodium hypochlorite. Therefore, it was not verified that the flume water was within the target range for free chlorine after the addition of the anti-microbial agent. Mr. J. Montiel stated that the free chlorine target range used

by the firm was a recommendation made by a consultant. Mr. J. Montiel did not have documentation of the consultant's recommendations.

The FDB RO noted the building and fixtures to be inadequate in that there was rust on fixtures, chipped paint, exposed foam insulation, and an accumulation of black residue on the walls (Attachment 24 Items #11,12 & Attachment 42A-B). Employee restrooms were observed to be inadequate and inaccessible (Attachment 24 Item # 6). Also, two portable toilets, located on the west side of the entry into the facility were in use by employees (Attachment 35B). The GCP facility was not equipped with a utensil or equipment washing sink (Attachment 25 Item #7). As noted on the RO dated October 8 and 9, 2003 item # 5, backflow devices were not present on hoses (Attachment 24).

Sampling

On October 8, 2003, FDA staff collected environmental samples that were submitted to the FDA Alameda laboratory for *E. coli* O157:H7 testing. All samples were negative for *E. coli* O157:H7 (Attachment 43). Sample collection methodology, handling, and transport information is contained in the FDA Collection Reports (Attachment 43).

On October 9, 2003, ERU staff collected six environmental samples from the processing area which were submitted to CDHS-FDB-Richmond Laboratory (Attachment 44). Sampling sources are noted on the Laboratory Analysis Request (LARS) forms (Attachment 44). The samples were collected aseptically using Solar Biologicals, Inc. (Lot # AL 03-5025, Exp. May 1, 2005) sponges with buffered peptone water. All samples were negative for *E. coli* O157:H7 (Attachment 45). These samples were collected after the firm had begun breakdown and sanitation of Line #1.

On October 9, 2003, FDA staff collected five, one-pound bags of salad products found on the firm's quality control shelf (Attachment 46). The production dates for these bags were 9/24/03, 9/25/03, 10/1/03, and 10/3/03. These samples were produced within the time frame of the outbreak. The samples were submitted to FDA-Irvine Laboratory and all samples were negative for *E. coli* O157:H7 (Attachment 47).

On October 9, 2003, FDA staff submitted 10 – five-pound bags of finished product (mixed iceberg lettuce and romaine) to the FDA –Irvine Laboratory. These samples were produced on October 8, 2003. The samples tested negative for the presence of enterohemorrhagic *E. coli* (EHEC) (Attachment 48).

GCP had last processed lettuce on Line #1 before 8 AM on October 8, 2003. GCP was processing diced red peppers on Line #2 at the time of the FDB-ERU investigational inspection on October 8, 2003 (Attachment 49A-B).

Recall

GCP issued a voluntary recall for all 70/30 lettuce mix and all salad mixes containing 70/30 lettuce mix on October 8, 2003 (Attachment 50). Mr. J. Montiel stated that all GCP accounts were notified of the recall by a phone call and a fax with the recall notification. On October 8, 2003, GCP discontinued processing all products on Line #1 and all salad production was halted. The Berry Man, Produce Available, and FTP (distributors of GCP products) contacted all of their accounts receiving the recalled product. The customers of the above distributors were instructed to either destroy the recalled product or return it to the distributor. Credit was given for all products on hand at the time of the recall.

On October 8, 2003, ERU staff contacted health departments in counties where schools and other point of services (POS) might have been supplied the recalled product. San Diego, Orange County, City of Long Beach, Santa Barbara, and Ventura County Health Departments were notified of the recall. FTP, The Berry Man, and Produce Available distribution lists indicated that schools within these counties received GCP Salad 3 Way and/or 4 Way Bite Size salads. ERU staff called customers of both The Berry Man and Produce Available to determine if they had been notified of the recall. ERU staff determined that both The Berry Man's and Produce Available's accounts had been notified of the recall.

FDB Regulatory Actions

On October 10, 2003, CDHS-FDB staff witnessed the voluntary condemnation and destruction at GCP of \$20,930 worth of various processed vegetables and salads (Attachment 51). GCP agreed at this time not to resume production until a scheduled office hearing was held with FDB on October 15, 2003.

Farm Environmental Investigations

DP, RR, and POVE identified 29 fields (Attachment 52) where the implicated iceberg lettuce and romaine had been harvested between September 2, 2003 and October 3, 2003. This extended time frame was chosen in order to ensure that ERU had information regarding any farms that may have supplied lettuce to GCP during the outbreak. As part of the outbreak investigation, ERU staff inspected all but one of the 29 fields. From these 29 fields, 14 fields were determined by CDHS-FDB to be high probability farms based on harvest dates. All of the "high probability farms" were inspected. One farm, the Metz Ranch, was not visited at the time of the other farm inspections because it was not initially identified in the traceback. DP notified ERU staff on January 26, 2003 that the Metz Ranch supplied romaine lettuce during the investigational time frame. Because Metz Ranch was classified as a "low probability farm", ERU staff decided not to visit the farm.

The high probability farms were determined by starting with the earliest case exposure date (September 27, 2003) and then subtracting the minimum and maximum harvest-to delivery times (2-11 days). Therefore, lettuce harvested September 15, 2003 through September 25, 2003 could have been available at PO on September 27, 2003, the first exposure date. Any farm that harvested lettuce between September 15 and 25, 2003, was identified by CDHS-FDB as a high probability farm (Attachment 53).

Diamond Produce

Farm Investigation

Diamond Produce contracted with growers throughout the Salinas area to grow iceberg lettuce during the broad time period of interest (September 2, 2003 - October 3, 2003). The iceberg lettuce included in this investigation, was planted and cultivated to maturity by DP contract growers. DP's crews harvested the iceberg lettuce crops using DP equipment. Harvested lettuce was placed into a plastic-lined bin at the field and then transported to 3-D Cooling (Salinas, California). 3-D Cooling was responsible for the cooling and cold storage of the product.

DP supplied ERU staff with information regarding the field locations and harvest dates for the iceberg lettuce. DP arranged for ERU staff to visit the lettuce fields that were the most likely sources for the lettuce implicated in the investigation. As part of the investigation, ERU staff visited farms and met with each field manager to obtain information about growing, harvesting, and shipping practices.

Although DP supplied romaine lettuce to GCP, DP did not have a prearranged contract with romaine growers. DP filled GCP orders by purchasing romaine from other produce firms. DP contracted with RR, Paul's Pac, and POVE to fill these GCP orders.

Growers for Diamond Produce

1-3. Ocean Mist Farms/ Sea Mist Farms – Sella 4A, 4D and 4E

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On October 22, 2003, Dr. Jennifer Thomas and Investigator Carol Myers conducted a farm investigation at Sella 4A, 4D, and 4E fields located in Castroville, California (Attachment 54). Mr. Zendejas and Mr. Ballesteros were present during the investigation. Sea Mist Farms is an affiliate of Ocean Mist Farms also located in Castroville. Sella 4A, 4D, and 4E are part of the larger 350 acre Ocean Mist Sella Ranch. Sella 4A, 4D, and Sella 4E were planted with iceberg lettuce seeds July 2, 2003, July 11, 2003, and July 1, 2003, respectively and their respective dates of harvest were September 10, 2003, September 17, 2003, and September 17, 2003. Because of the harvest date of September 17, 2003, Sella fields 4D and 4E were identified by CDHS-FDB as high probability farms.

Each of the Sella fields identified in this investigation was harvested twice for iceberg lettuce. It is not uncommon in the produce industry for a field of iceberg lettuce to be harvested more than once. The first harvest produces market quality head-lettuce and the second harvest produces

lesser quality lettuce that is used for processing. Valley Pride, a contractor harvesting company, completed the first harvest of the fields for Sea Mist. Approximately two days after the Sea Mist harvest, DP finished the second harvest at the Sella fields.

Sea Mist employs 15 workers on the Sella Ranches. The employees are primarily responsible for soil preparation, planting, irrigation, and thinning. According to Mr. Zendejas, no employees were ill during this season. However, no employee records were provided to the ERU staff. Mr. Zendejas reported that handwashing facilities and toilets are provided to the workers when they are working on any of the Sea Mist ranches.

Mr. Zendejas reported that no animal manure, compost, or biosolids were used to amend the soil on the Sella Ranches. There were no unusual weather conditions and the fields were not exposed to flooding during the growing or harvesting period. The fields were watered using overhead sprinklers during the entire growing period. Sea Mist owns all the equipment used on the farm for the cultivating of the crop (tractors, disks, blades, etc.) The equipment is not leased to other growers and is washed down twice a year.

The Sella fields are supplied with Monterey County Recycling Projects (MCWRP) recycled water. The Monterey Regional Water Pollution Control Agency (MRWPCA) tests the recycled water for coliform and fecal coliform every seven days and pathogen data is collected three times a year (Attachment 55).

On October 22, 2003, ERU staff observed approximately 200 wild, local-resident geese (*Branta canadensis minima*) on Sella fields (Attachment 56A-B). Mr. Zendejas reported that this was the first year he had noticed the geese and that the geese had been present on the Sella fields since the germination of the lettuce. On December 2, 2003, Lorraine Dixon, FDA, Cody Stemler, United States Department of Agriculture (USDA) Wildlife Specialist, Dr. Thomas, Investigator Myers, and other CDHS staff revisited the Sella fields to collect environmental samples. The team collected a total of eight composite samples, consisting of 32 drag swabs, from Sella 4D and Sella 4E. Control samples were taken at the time of the sampling consisting of an open and closed gloved sample and an open and closed drag-swab sample.

Each field was visually sectioned into four smaller sampling sections. Each sectioned area was sampled using drag swabs. The drag swab was a sterile four ply, three-inch by three-inch cotton gauze swab (Solar-Cult form Solar Biologics, Inc., pre-moistened with double strength skim milk) attached to a sterile cord. Using aseptic technique, the drag swab was pulled on the ground to the side of the sampler in one of the four sections of each Sella field. Two samplers walked approximately 60 yards into each section of the field, each pulling a drag swab. The two swabs were placed into the same whirl-pak bag. The procedure, using two additional swabs, was repeated for the same section and added to the whirl-pak bag with the first two swabs, thus producing one composite sample. A total of four composite samples consisting of a total of 16 drag swabs were collected from each of the Sella fields, thus yielding 8 composite samples. The samples were immediately placed on blue ice in an ice chest. On December 2, 2003, using aseptic technique, a sample of goose feces was collected from the soil, placed in a sterile whirl-pak bag, and immediately placed on ice. All samples were submitted to FDA, Alameda Laboratory for *E. coli* O157:H7 analysis within 12 hours.

Three composite drag swabs collected from the Sella farm were positive for *E. coli* O157:H7 using PCR amplification (Attachment 57). However, *E. coli* O157:H7 was not recovered using Bacteriological Analytical Manual (BAM) culture methodology (Attachment 57). Composite geese fecal samples tested positive for *E. coli* O157:H7 on both the PCR amplification and BAM culture methodology. The PFGE pattern of the isolate collected from the geese did not match the PFGE pattern associated with case-patients in the outbreak.

4-6. Francioni Brothers Inc. - Wing Ranch 301A, 307B, and 303C

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Investigator Myers and Dr. Thomas conducted a farm investigation at the Wing Ranch on October 21, 2003. Mr. Francioni and Mr. Ballesteros were present during the investigation. The Wing Ranch is located on the east side of Highway 101 north of Gonzales, California. Wing Ranch is 290 acres, divided into 18 fields and is leased by Francioni Brothers, Inc. (Attachment 58). Three fields were implicated in the outbreak traceback: Wing 301A (five acres), Wing 307B (eight acres) and Wing 303C (eight acres). Francioni Brothers, Inc. planted Wing 301A on July 7, Wing 307B on July 12, and Wing 303C field on July 14, 2003. All of the fields were planted with lettuce seed. DP harvested the iceberg lettuce crop on Wing 301A on September 11, 2003, Wing 307B on September 29, 2003, and 303C on September 18, 2003. Because Wing 303C was harvested on September 18, the field was identified by CDHS-FDB as a high probability farm.

Francioni Brothers employs and contracts several individuals for their operations. The employees are primarily responsible for soil preparation, planting, irrigating, and thinning. According to Mr. Francioni, no employees were ill during the season. However, no employee records were provided to the ERU staff. Francioni Brothers or the contracting crew provided handwashing facilities and toilets to the workers.

Mr. Francioni reported that there were no unusual weather conditions and the fields were not exposed to flooding during the growing or harvesting period. Mr. Francioni did not remember seeing any wildlife on the Wing Ranch during the 2003 season. However, FDB investigators did notice small mammal tracks located around the field.

Francioni Brothers owns all the equipment used on the farm for the cultivating of the crop (tractors, disks, blades, etc.) The equipment is not leased to other growers and is cleaned by a water wash as needed and steam cleaned on an annual basis.

Mr. Francioni informed the ERU staff that no manure or compost had been applied to the Wing fields in several years. Cover crops, such as rye grass, had been planted and disked into the fields on a yearly basis. Two wells, the East Well and the West Well, supply irrigation water to these fields. Both wellheads appeared to be properly sealed. The west well supplies 80% of the water for the entire Wing Ranch. Sprinklers were used until germination and then drip irrigation was used until harvest.

A January 21, 2003, well water laboratory analysis reported from Soil Control Labs (Watsonville, California) showed 300 MPN total coliform/100 ml for the Wing West Well and 36 MPN total coliform/ 100 ml for the Wing East Well (Attachment 59). Because of the laboratory results, ERU sampled the water for analysis. On December 15, 2003, ERU staff collected two-liters of water from the West Well in order to evaluate the water quality. CDHS-FDB-Richmond Laboratory analyzed the sample and reported that the sample contained 2.0 MPN/100 ml of total coliform and less than 2.0 MPN for fecal coliforms and *E. coli* (Attachment 60).

7. Francioni Brothers Inc. – Hartnell 509

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Investigator Myers and Dr. Thomas conducted a farm investigation at the Hartnell Ranch on October 21, 2003. Mr. Francioni and Mr. Ballesteros were present during the investigation. Hartnell Ranch is located approximately one-quarter mile east of the Salinas Airport. Francioni Brothers, Inc. leases the 100-acre Hartnell Ranch, which is divided into 9 fields (Attachment 61). The 10.2 acre Hartnell-509 field was planted on June 2, 2003, and harvested by DP on September 9, 2003. Because of the harvest date of September 9, 2003, Hartnell-509 was identified by CDHS-FDB as a low probability farm.

The workers on the Hartnell Ranch are employed or contracted by Francioni Brothers to work on all of their ranches. The employees are primarily responsible for soil preparation, planting, irrigating, and thinning. According to Mr. Francioni, no employees were ill during the season. However, no employee records were provided to ERU staff. Francioni Brothers or the contracting crew provided handwashing facilities and toilets to the workers.

Mr. Francioni reported that there were no unusual weather conditions and the fields were not exposed to flooding during the growing or harvesting period. Mr. Francioni reported that he does not see wildlife on the farm. The investigative staff observed two dogs on the farm.

Franscioni Brothers owns all the equipment used on the farm for the cultivating of the crop (tractors, disks, blades, etc.). The equipment is not leased to other growers and is cleaned by a water wash as needed and steam cleaned on an annual basis. A permanent toilet and handwashing facility is located on the ranch. Contract crews supply portable toilets and handwashing facilities when working in the fields.

Mr. Franscioni told investigative staff that no manure or compost had been applied to the Hartnell fields for at least ten years. Cover crops, such as rye grass, had been planted and disked into the fields on a yearly basis. The lettuce crop was watered by overhead sprinklers until germination and then drip irrigated until harvest.

The Hartnell Ranch has one well and ERU staff observed that the wellhead was sealed. A January 21, 2003 Soil Control Lab (Salinas, California) report showed 25 MPN/100 ml total coliform for the Hartnell well (Attachment 59).

8. Barrett Ranch 902B

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On November 5, 2003, Dr. Jennifer Thomas and Investigator Carol Myers conducted a farm investigation at Barrett 902B located west of Gonzales, California. Mr. Franscioni and Mr. Ballesteros were present during the investigation. Barrett 902B is approximately 4.5 acres and is part of the larger 19.1 acre Barrett Ranch 902 (Attachment 62). Barrett 902B was planted with romaine seeds on July 23, 2003, and harvested by DP on September 24, 2003. Because of the September 24, 2003, harvest date, Barrett 902B was identified by CDHS-FDB as a high probability farm.

Franscioni Brothers employs two workers for this farm. Contract crews are also hired for thinning. The employees are primarily responsible for soil preparation, planting, irrigating, and thinning. According to Mr. Franscioni, no employees were ill during the season. However, no employee records were provided to the ERU staff. Franscioni Brothers or the contracting crew provided handwashing facilities and toilets to the workers.

Mr. Franscioni reported that there were no unusual weather conditions and the fields were not exposed to flooding during the 2003 growing or harvesting period. The ranch is located approximately one-quarter mile east of the Salinas River and therefore is subject to flooding during flood years. The entire ranch was flooded (6-7 feet of water) in the flood years of 1995 and 1998. After the 1998 flood, river sand had to be hauled off of the ranch before farming

could resume. The City of Gonzales maintains sewage ponds that lie between the Salinas River and Barrett Ranch. These ponds were flooded by Salinas River water during the flood of 1998.

Mr. Francioni did not remember seeing any wildlife on the Barrett Ranch during the 2003 season. Cody Stemler, USDA, observed a deer carcass, and coyote and feral cat signs near the City of Gonzales sewage ponds on the day of this investigation. The Barrett Ranch is surrounded by farmland.

Francioni Brothers owns all the equipment used on the farm for the cultivating of the crop (tractors, disks, blades, etc.). The equipment is not leased to other growers and is cleaned by a water wash as needed. A permanent toilet and handwashing facility is located on the ranch. Contract crews supply portable toilets and handwashing facilities when working in the fields.

Mr. Francioni told investigative staff that no manure or compost had been applied to the Barrett Ranch fields for the ten years Francioni Brothers have leased the land. Cover crops, such as mustard, had been planted and disked into the fields on a yearly basis. The lettuce crop was watered by overhead sprinklers until germination and then drip irrigated until harvest.

Barrett Ranch Well #2 was used to supply this field during the growing season. Well #2 was tested by Soil Control Lab (Salinas, California) on January 21, 2003 (Attachment 59). The results showed that Well #2 had a total coliform level of 280 MPN/100ml. Because of the coliform levels reported by Soil Control Lab, ERU staff sampled the well water. On December 15, 2003, FDB investigative staff collected two liters of water from Well #2 and submitted it to the CDHS-FDB-Richmond Laboratory for total coliform, fecal coliform, and *E. coli* analysis. The analysis reported coliform levels of 170 MPN/100 ml, fecal coliform levels of 4 MPN/100 ml, and the absence of *E. coli* (Attachment 60). On January 7, 2004, Mr. Francioni was notified of the FDB test results and stated he would have the well treated and follow a testing program to determine if the level of coliforms had decreased.

9. Bassetti Ranch – Home 3-2A

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On October 21, 2003, Investigator Myers and Dr. Thomas conducted a farm investigation at Bassetti Ranch – Home 3-2A. Mr. Bassetti and Mr. Ballesteros were present during the investigation. The ranch is 10.4 acres located near Greenfield, California (Attachment 63) and is owned by Mr. Bassetti. Home 3-2A was planted with iceberg seed on July 16, 2003, and harvested by DP on September 24, 2003. Because of the September 24, 2003, harvest date, the Bassetti Ranch was identified by CDHS-FDB as a high probability farm.

Mr. Bassetti employs approximately 25 workers on the Home 3-2A and other Bassetti ranches. The employees are primarily responsible for soil preparation, planting, irrigating, and thinning. According to Mr. Bassetti, no employees were ill during this season. However, no employee records were provided to the ERU staff. Mr. Bassetti reported that handwashing facilities and toilets are provided to the workers when they are at Home 3-2A. ERU did not observe toilets or handwashing facilities, however no employees were present at the field during the investigation.

Mr. Bassetti reported that no animal manure, compost, or biosolids were used to amend the soil on the Home 3-2A ranch. There were no unusual weather conditions and the fields were not exposed to flooding during the growing or harvesting period. Mr. Bassetti had noted some wildlife such as deer and raccoons near the river, but did not remember seeing any wildlife on Home 3-2A this season. The Salinas River is approximately one-half mile to the east of the ranch.

Mr. Bassetti owns all the equipment used on the farm for the cultivating of the crop (tractors, disks, blades, etc.). The equipment is not leased to other growers and is cleaned by a water wash and steam as needed.

Well water was used for furrow row irrigation during the first 90 days of the growing season. Overhead sprinklers and drip irrigation lines watered the field for the remainder of the growing period. On February 25, 2003 Primus Laboratory, Santa Maria, California tested the Bassetti Ranch well. The test results were negative for *E. coli*, total coliform, and Salmonella (Attachment 64).

10. Guidotti Brothers – Jim-4N

Contacts:

Milton and Jim Guidotti, Partners
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(831) 678-3134

Frank Ballesteros, DP Sales Manager
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(831) 758-3758

On October 21, 2003, Dr. Thomas and Investigator Myers conducted a farm investigation at Jim-4N farm. Mr. Milton Guidotti and Mr. Ballesteros were present during the investigation. The 13-acre farm is located approximately three-quarter miles south of Soledad, California (Attachment 65). The field was planted with iceberg seed on July 14, 2003, and DP harvested Jim-4N on September 23, 2003. Because of the September 23, 2003, harvest date, Jim-4N was identified by CDHS-FDB as a high probability farm.

Guidotti Farms employs approximately 12 workers. The employees are primarily responsible for soil preparation, planting, irrigating, and thinning. According to Mr. Guidotti, no employees

were ill during this season. However, no employee records were provided to the ERU staff. Handwashing facilities and toilets are provided to the workers when they are at Jim-4.

Mr. Jim Guidotti reported that mushroom compost was applied by Associated Tagline, Salinas, California to Jim-4N in November 2002 and 2003. Mr. Jim Guidotti stated that cow manure supplied by Associated Tagline was used approximately two years ago (2001) on Jim-4N. The compost and manure were mixed with gypsum before being spread onto the field. Associated Tagline used their equipment to spread the amendments. The Guidotti's raise pigs and have used pig manure on other fields on the Guidotti Ranch within the past two years. Mr. Jim Guidotti reported that manure is stored on the ranch, but not on fields near or where lettuce is grown. ERU staff did not observe a manure or compost pile near Jim-4N.

There were no unusual weather conditions and the field was not exposed to flooding during the growing or harvesting period. On December 2, 2003, Cody Stemler, USDA, observed signs of deer, coyote, skunk, opossum, fox, raccoons, mice, and rabbits on the fields.

Guidotti Farms owns all the equipment used on the farm for the cultivating of the crop (tractors, disks, blades, etc.) The equipment is not leased to other growers and is cleaned by a water wash as needed.

There are two wells that supply Jim-4N with water. The field was watered with overhead sprinklers for the first 10 days post-planting and then furrow irrigated until harvest. Water tested by Primus Laboratory on April 30, 2003, from the Guidotti wells was negative for coliforms and *E. coli* (Attachment 66).

11. Guidotti Brothers – Metz 1

Contacts:

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Frank Ballesteros, DP Sales Manager
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On January 26, 2003, Mr. Ballesteros faxed documents to ERU staff confirming the identity of Metz 1, a farm that supplied romaine to GCP during the time frame of concern. On January 27, 2003, Investigator Myers had a telephone conversation with Jim Guidotti to obtain farm information for Metz 1. Bart and Jeremy Guidotti manage the ranch for Guidotti Brothers. The 70 acre Metz Ranch is located northeast of Soledad, California. Metz 1 is nine acres and DP harvested approximately two acres of romaine on September 26, 2003 (Attachment 67). The Metz 1 was identified by CDHS-FDB as a low probability farm.

Two employees are primarily responsible for soil preparation, planting, and irrigation. Thinning crews are hired through local labor contractors. According to Mr. Guidotti, no employees were

ill during this season. However, no employee records were provided to the ERU staff. One portable toilet with handwashing facilities was located on the ranch and maintained by an independent company.

Mr. Guidotti reported that no animal manure or compost was used to amend the soil since his company began leasing the ranch in 2001. There were no unusual weather conditions and the fields were not exposed to flooding during the growing or harvest period. Mr. Guidotti stated that deer and wild pigs had been observed in the area.

Guidotti Brothers own all of the equipment used on the ranch for the cultivating of the crop (tractors, disks, blades, etc.). Equipment used for Metz Ranch is not used for other ranches and is stored on the ranch. The equipment is cleaned by a water wash as needed.

Microbial test results were not available for the one well that supplies the Metz Ranch. The romaine crop was watered with over head sprinklers during the growing period.

12-13. Domingos Brothers – Tomasini 5N, 5S

Contacts:

John and Richard Domingos, Owners
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Frank Ballesteros, DP Sales Manager
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(831) 758-3758

On October 21, 2003, Dr. Thomas and Investigator Myers conducted an environmental investigation of Tomasini Ranch. Mr. John and Richard Domingos and Mr. Ballesteros were present during the investigation. The 68-acre Tomasini Ranch is southeast of Soledad, California off of Hwy 101. Tomasini Ranch 5 is ten acres, which is divided into fields 5N and 5S (Attachment 68). Iceberg seed was planted on July 2, 2003, and harvested by DP on September 23, 2003. Because of the harvest date, the Tomasini Ranch 5 was identified by CDHS-FDB as a high probability farm.

Two employees work the Tomasini Ranch. The employees are primarily responsible for soil preparation, planting, and irrigating. The Domingos Brothers hire thinning crews through local labor contractors. According to John Domingos, no employees were ill during the 2003 season. However, no employee records were provided to the ERU staff. A portable toilet, located approximately one mile from the ranch, was provided for the two employees. Handwashing facilities were not provided.

The Domingos brothers reported that they have farmed this ranch for nine consecutive years and have never applied animal manure or compost to the fields of Tomasini Ranch. There were no unusual weather conditions or flooding during the 2003 growing season. Mr. John Domingos

stated that he had not noticed wildlife on the ranch; however, the Salinas River is approximately one-quarter mile west of the ranch and is abundant with wildlife.

A well supplies water to the Tomasini Ranch. The wellhead appeared to be appropriately sealed on a cement base. The field was watered with overhead sprinklers and then drip irrigation. Mr. John Domingos did not have documentation for well testing. On December 15, ERU staff collected two liters of well water and submitted the samples to the CDHS-FDB-Richmond Laboratory for testing. The results showed 2.0 MPN/100 ml coliform and less than 2 MPN/100 ml for both fecal coliform and *E. coli* (Attachment 60).

14-15. Huntington Farms – Huntington-Pryor-26N, 26S

Contacts:

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Frank Ballesteros, DP Sales Manager
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On October 21, 2003, Investigator Myers and Dr. Thomas conducted a farm investigation at Huntington Ranch – 26N and 26S. Mr. Anderson and Mr. Ballesteros were present during the investigation. The Huntington-Pryor Ranch is located near Soledad, California. The Huntington-Pryor fields 26N and 26S are each 13 acres (Attachment 69). Huntington Farms planted 26N on June 27, 2003, and 26S on June 22, 2003. On September 9, 2003, DP harvested the iceberg lettuce crop on 26N and 26S. Because of the September 9, 2003, harvest date, the Huntington-Pryor Ranch was identified by CDHS-FDB a low probability farm.

Huntington Farms employs approximately 24 workers. The employees are primarily responsible for soil preparation, planting, irrigating, and thinning. According to Mr. Anderson, no employees were ill during this season. However, no employee records were provided to the ERU staff. Handwashing facilities and toilets are provided to the workers when they are at the Huntington-Pryor fields. Two toilet facilities were noted during the investigation. The facilities were clean and supplied with water, soap, and towels.

Mr. Anderson reported that no animal manure, compost, or biosolids were used to amend the soil on the two fields in 2003. Compost supplied by The Good Humus Man (Salinas, California) was used on the fields in 2002. Mr. Anderson reported that the compost was made from green waste such as vegetable cutting, culls, and woodchips. There were no unusual weather conditions and the fields were not exposed to flooding during the growing or harvesting periods. Mr. Anderson had noted some raccoons, bobcat, and a deer on the fields this season.

Farm equipment is stored on the Pryor Ranch and is shared between other Huntington ranches. Mr. Anderson stated that the equipment is washed once or twice a year with a high pressure wash with hot water.

Huntington-Pryor Ranch Well #6 was used to supply this field with water during the growing season. The field was irrigated with overhead sprinklers and furrow irrigation. On June 20, 2003, Davis Fresh Technologies, Davis, California tested the Huntington-Pryor Ranch well. The test results were negative for *E. coli* and coliforms (Attachment 70).

16-17. Huntington Farms: Hilltown 5 and 6

Contacts:

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Frank Ballesteros, DP Sales Manager
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(831) 758-3758

On October 22, 2003, Investigator Myers and Dr. Thomas conducted a farm investigation at Hilltown 5 and 6. Mr. Huntington and Mr. Ballesteros were present during the investigation. The 103-acre Hilltown Ranch is located near Soledad, California. Hilltown 5 and 6 (12.4 and 8.9 acres respectively) were planted with iceberg seed on July 5, 2003, and July 19, 2003, respectively (Attachment 71). On October 2, 2003, DP harvested the second cut of iceberg lettuce. Because of the late date of harvest, the Huntington-Hilltown Ranch was identified by CDHS-FDB as a low probability farm.

Huntington Farms employs five workers for the Hilltown Ranch. The employees are primarily responsible for soil preparation, planting, and irrigating. Thinning crews are hired through local labor contractors. According to Mr. Huntington, no employees were ill during this season. However, employee records were not provided to the ERU staff. One portable toilet and handwashing facility was located on the ranch.

The Hilltown 5 and 6 fields were irrigated with overhead sprinklers the first 50 days of growth and then furrow irrigated until harvest. Mr. Huntington stated that no manure or compost had been applied to the Hilltown Ranch in more than five years. Huntington Farms share equipment from one ranch to another. Mr. Huntington stated that the equipment is washed once or twice a year with a high hot water pressure wash.

Hilltown fields 5 and 6 are supplied with well water. On June 17, 2003, Davis Fresh Technologies, Davis, California tested Well #1, the well used to water Hilltown Ranch 5 and 6. The test results were negative for *E. coli* and coliforms (Attachment 72).

18. Fabretti & Dedini (F & D) – Home Ranch

Contacts:

Stan Hitchcock, Partner
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Frank Ballesteros, DP Sales Manager
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(831) 758-3758

On October 21, 2003, Investigator Myers and Dr. Thomas conducted a farm investigation at F & D Home Ranch. Mr. Hitchcock and Mr. Ballesteros were present during the investigation. Home Ranch is located off Hwy 101 south of Greenfield, California. The ranch is divided into 16 fields. Field 9 comprises 50 acres and field 9 South (9S) is 12 acres (Attachment 73). Home Ranch 9S was planted with iceberg seed on July 2, 2003, and harvested by DP on September 8, 2003. Because of the harvest date, the F & D Ranch was identified by CDHS-FDB as a low probability farm.

F & D has two employees responsible for soil preparation, planting, and watering Home Ranch 9S. Thinning crews are sometimes hired through local labor contractors. Toilets and handwashing facilities are located on the ranch. No soap or towels were available at the toilet station on October 21, 2003. There were no reported employee illnesses during the 2003 season. However, employee records were not provided to the ERU staff.

Mr. Hitchcock reported that no animal manure, compost, or biosolids were used to amend the soil on Home Ranch 9S. There were no unusual weather conditions or flooding during the growing or harvesting period. Mr. Hitchcock reported that wildlife had not been observed in the field. The Salinas River is approximately three-quarters of a mile to the east of the ranch.

F & D owns all of the equipment used on the farm for cultivating crops (tractors, disks, blades, etc.). The equipment is stored on Home Ranch. Mr. Hitchcock stated that the equipment is water washed occasionally. The equipment is not leased or used for any other fields or ranches.

A well, on a cement base with a sealed wellhead, supplies water for Home Ranch. Overhead sprinklers irrigated the romaine crop for one month after germination and then drip irrigated was used until harvest. On August 8, 1999, A & L Western Agricultural Laboratories (Modesto, California) tested the well for mineral and dissolved solids, but did not do any microbiological assays (Attachment 74).

Diamond Produce (DP) Harvesting

DP used their harvesting crews to cut and core iceberg lettuce in the field. Typically a harvest crew consists of 15 harvesters, two quality assurance workers, and two supervisors. A copy of DP's Food Safety Program can be viewed in Attachment 75. All field workers in contact with product wear hair coverings, gloves, and plastic aprons. The harvesting tool used by DP has a stainless steel blade at one end with a plastic handle and a coring blade at the opposite end. A field worker, using the harvesting tool, cuts the iceberg lettuce from the stem, cores the lettuce, and places the cored head on the harvest belt. The lettuce then moves along this belt where

workers remove the outer leaves. After the outer leaves are removed, two quality assurance workers spray the lettuce with diluted liquid sodium hypochlorite. The QA person, using test strips, measures and records the concentration of the chlorine spray approximately three times a day. The target concentration for this spray was 200 PPM total chlorine. This spray was tested by ERU staff with chlorine test strips (“Chlorine Test Papers” Code 4250-BJ, LaMotte), to have a total chlorine level of 200 PPM. The lettuce is then transferred to plastic-lined cardboard bins sitting on a truck. Attachment 76A-I contains photographs of iceberg lettuce harvesting.

According to DP management, all harvest equipment (except the knives) were cleaned and sanitized three times per day. The belt was first pressure washed with farm water and scrubbed with a chlorine solution with a pH of 6.8. However, on the day of the visit, the brushes used for cleaning were dry and did not appear to have been used that day (Attachment 77A).

The harvest supervisor reported that the harvest tools were cleaned at the end of the work day and stored at the workers’ home each night. DP supplied three-gallon buckets filled with diluted sodium hypochlorite solution for storing and cleaning the tools during the day. On the day of the investigation, ERU staff were taken to a pick up truck at the end of the field being harvested to observe a bucket of chlorinated water. The water in the bucket was greater than 200 PPM, measured with chlorine test strips (“Chlorine Test Papers” Code 4250-BJ, LaMotte). It was reported by the harvest supervisor that the tools were cleaned by dipping and swirling the blade portion of the tool in diluted sodium hypochlorite. The tools were not scrubbed or washed with any additional products. The workers’ gloves are not washed or changed on a scheduled time basis. During breaks, the gloves are reportedly placed into the same buckets with the tools.

On October 21, 2003, Investigator Myers, Dr. Thomas, and Mr. Ballesteros observed the harvesting of an iceberg lettuce crop. All harvest crew workers coming in contact with the product were observed wearing hair coverings, gloves, and aprons. A few of the workers wore sleeve protectors. The portable toilet was equipped with soap, water, and single use towels. The water spigot, used for handwashing, could only be operated by pushing and continually holding a button down (Attachment 77B).

3-D Cooling - Environmental Investigation

Contact:

Larry Baze, Plant Manager
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On October 2, 2003, Investigator Myers and Dr. Thomas visited 3-D Cooling. Bills of lading supplied by DP indicated that lettuce distributed through DP was cooled at this facility (Attachment 11A, 11C).

3-D Cooling leases the cooling facility from Andrew Smith, P.O. Box 7296, Spreckles, California 93962. The approximately two acre facility contains three hydrovacuum/vacuum tubes (VC-2, T1, and T2), a cold storage room with loading docks, and a covered staging pad (Attachment 78A-C). Two of the tubes (VC-2 and T2) are strictly dry vacuum tubes and

therefore no water was used in the cooling process. T1 was used both as a wet (hydrovacuum) and a dry vacuum tube and had water in the reservoir at the time of the FDB investigation (Attachment 79A-D). VC-2 was leased from Andrew Smith Company and tubes T1 and T2 are owned by 3-D Cooling. T2 is not used to cool DP lettuce. Product is generally cooled from 8:00 AM to noon.

Cooling of romaine lettuce at this facility occurred by creating a negative pressure inside a sealed piece of equipment, frequently referred to as a “vacuum tube” (even though some are not cylindrical) or “hydrovacs”. “Wet” or “dry” hydrovac treatments are applied depending upon the product and type of packaging. Wet treatment includes an application of water during the cooling cycle. Dry treatment does not involve an application of water although water may be present in the reservoir of the tube. For both processes, the goal is to rapidly cool the product to approximately 34°F to preserve the shelf life.

The wet hydrovac process can cool several hundred cases of product at a time in the vacuum “tube”. The “tube” resembles a railroad car with large doors at both ends to allow entrance and exit of product loads. The doors are sealed and air is removed from the chamber, beginning the cooling process. As the atmospheric pressure decreases within the “tube”, the rate of evaporation of moisture in and on the product increases, rapidly cooling the product. At some point or points during the wet hydrovac process (procedures vary by firm), water is pumped from a reservoir in the bottom of the tube to the top of the tube and applied through nozzles to the product. This water circulates down through the hundreds of cases of product during the cooling cycle. The water is added to replenish moisture lost during the vacuum cooling process. Water in the reservoir may be replenished throughout the day. The time required to reach 34°F is dependent upon initial temperature and density of the product, the number of cases being cooled, and the efficiency of the mechanical equipment. Internal temperatures of the “tube” and atmospheric pressure are monitored during the cooling process.

Dry vacuum treatment is essentially the same process as described above without the direct application of water. However, in some cases, there may be water present in the reservoir of the vacuum tube, which may result in some vaporization during the negative pressure cooling cycle.

DP lettuce was primarily cooled in VC-2, but during busy days, T1 was also used. Trucks brought lettuce boxed or in bins to the cooler and either immediately placed them on the hydrovacuum/vacuum tube loader or on the staging pad. DP lettuce was cooled for approximately 35-45 minutes. At the time of the FDB-ERU inspection, T1 had water in the reservoir. Mr. Baze reported that the tube was used as a dry vacuum tube for cooling DP lettuce.

The vacuum tube T1 was found to be dirty with organic debris in the reservoir (Attachment 79C). VC-2 was in use for Andrew Smith product while the ERU staff member was at the facility.

Mr. Baze stated that liquid sodium hypochlorite is added to the T1 reservoir. During the visit, ERU staff noted that the liquid chlorine was stored in an unlabeled plastic juice container. Mr. Baze did not know the concentration or the brand of the chlorine. Because the bottle was unmarked, ERU had no method to confirm any information regarding the chlorine. Mr. Baze

stated that he added about an eighth of a cup of liquid chlorine to the reservoir every morning, however; ERU staff did not observe the chlorine being measured and a measuring cup was not available on the day of the investigation. The firm did not test the chlorine levels in the reservoir water and did not have any equipment or test strips available to test chlorine levels. The firm did not have SOPs for the chlorination of the reservoir water. Records were not kept documenting the addition of chlorine to the reservoir. ERU staff, using an ORP Tester (Double Junction Model/356050-02) recorded an ORP reading of 299 mV for the T1 reservoir water.

The facility was supplied with well water from the El Camino Water Company, Salinas, California. The well was located approximately one-half mile southeast of the facility. August, September, and October test results for the private well were “positive” for total coliform at two collection points in the system and at the well. The pressure tank also tested “present” for total coliforms. These same test results were “absent” for *E. coli* (Attachment 80).

After the cooling cycle is completed, the pallets of lettuce were immediately transferred to the forced-air cold storage room. This room was found to be clean and orderly (Attachments 78A, 78C). All products were stored off of the floor on pallets. Nitrogen gas was added to the 900 lbs plastic bins of lettuce and then the plastic bin-liner was sealed. Before loading trucks with cooled product, the loader was required to make a visual inspection of the trucks. If the trucks were found to be dirty or have torn chutes, the loader was to reject the truck. No SOPs or “check sheets” were provided to document this process.

River Ranch Farm Investigations

Farm Environmental Investigation - River Ranch

RR harvested four romaine fields during the outbreak time frame that were sold under contract to DP. The four romaine fields, Chinn Ranch 3-5A, Callaghan Ranch 19-A, Cassin Ranch-2, and Lukrich Ranch-2 were harvested by RR using RR crews and equipment. Once harvested, RR transported the product to 3-D Cooling for cooling and cold storage. River Ranch was not harvesting romaine lettuce during the time of this investigation and therefore harvesting practices were not observed.

19. Comgro - Chinn Ranch 3-5A

Contacts:

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Brian Snow, Growers Relations, River Ranch Fresh Foods, LLC
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Investigator Myers and Dr. Thomas conducted a farm investigation of Chinn Ranch 3-5A on November 5, 2003. Mr. Massa and Mr. Snow were present during the investigation. The Chinn Ranch 3 is located northwest of Salinas, California (Attachment 81). Comgro is a custom grower that leases 13 ranches, approximating 2,100 acres, in the Salinas Valley. Comgro also operates commercial composting facilities in Hollister, California and Salinas, California. Produce companies, such as RR, contract with Comgro to grow specific produce crops. Chinn 3-5A is one of 21 fields that comprise Chinn Ranch 3 (Attachment 82). Chinn 3-5A was planted with romaine seeds on July 26, 2003, and harvested by RR on September 19, 2003. Because of the harvest date, Chinn Ranch 3-5A was identified by CDHS-FDB as a high probability farm.

Comgro employs and contracts several individuals for Comgro operations. For example, Comgro hires local contractors for the thinning of crops. However, Comgro does not employ harvesting crews and requires that the customer harvest crops. Comgro shares farming equipment among their ranches. The equipment is washed and pressured washed when needed.

Mr. Massa reported that there were no unusual weather conditions during the growing season. Chinn Ranch 3-5A is bordered by farmland on three sides and the Santa Rita Creek on the north side. Santa Rita Creek is a ditch that carries municipal and agriculture runoff water into the Monterey Bay. Yearly rains cause the creek to flood certain fields on the Chinn Ranch 3, however, Chinn Ranch 3-5A did not flood in 2003 according to Mr. Massa.

Chinn Ranch 3 is located on the outskirts of Salinas and Mr. Massa did not recall seeing wildlife on the fields. In November 2002, three tons per acre of grape pumice compost and one ton per acre of sugar beet lime were added to Chinn Ranch 3-5A. Mr. Fontes, Comgro partner, reported that no composted manure had been applied to Chinn Ranch 3-5A since 2000, at which time composted chicken manure was added.

Chinn Ranch 3 fields 1-6 are supplied with a well. Sprinklers irrigated the romaine crop grown on Chinn Ranch 3-5A with well water for the entire growing period. Monterey Bay Analytical Services analyzed the Chinn well water for *E. coli* and coliforms. The test results dated June 30, 2003, showed no fecal or total coliforms (Attachment 83).

Monterey County Water Resource Agency (MCWRA) is responsible for the maintenance of the Santa Rita Creek. During the rainy season, fields of the Chinn Ranch have flooded due to the flooding of the Santa Rita Creek. Mr. Fontes reported that a half-inch of rain is enough to cause the ditch to overflow and flood certain fields of Chinn Ranch 3. Fields of Chinn Ranch 3 can also be flooded when the pumping station located opposite Chinn Ranch 3-8 malfunctions. Mr. Fontes reported that with approximately one inch of rainfall the Santa Rita Creek can overflow onto Chinn Ranch 3-5A. Chinn Ranch 3-5A did not flood in 2003.

In May 2003, the ditch overflowed onto Chinn Ranch 3-8. A water sample was collected from the ditch by Monterey County Environmental Health staff. The 100 ml sample was collected 1,000 feet upstream of the Santa Rita Creek pump at Chinn Ranch 3 and tested by Monterey County Health Department. Results for fecal coliform revealed 3,000 MPN/100ml and total coliform greater than 24,182 MPN/100 ml (Attachment 84).

The Chinn Ranch was identified as a possible supplier of lettuce and spinach in two other *E. coli* O157:H7 outbreaks. In a July 2002 outbreak, Chinn Ranch 3-3 and Chinn Ranch 3-12 were two of the nine fields that supplied lettuce implicated in the outbreak. In an October 2003 outbreak, Chinn Ranch 3-8A was identified as one of the five fields that supplied spinach implicated in the outbreak.

20. Callaghan Ranch 19-A

Contacts:

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Investigator Myers and Dr. Thomas conducted a farm investigation at the Callaghan Ranch, field 19-A on November 5, 2003. Mr. Andrus and Mr. Snow were present for the investigation. Callaghan Ranch is located east of Hwy 101 off of Gloria Road, Gonzales, California. Callaghan 19-A is 7.2 acres and is one of 20 fields that comprise the Callaghan Ranch (Attachment 85). Callaghan Ranch was planted with romaine seeds on July 15, 2003. River Ranch harvested 3.6 acres of romaine from Callaghan Ranch 19-A on September 15, 2003. Because of the September 15, 2003, harvest date, CDHS-FDB classified Callaghan Ranch 19-A as a high probability farm.

Andrus Farms has three full time employees and hires workers through local contractors for cultivating and thinning the Callaghan Ranch. According to Mr. Andrus, no employees were ill during this season. However, no employee records were provided to the ERU staff. On the day of the ERU inspection, toilet facilities were not available, however, there were no workers on the ranch.

Mr. Andrus reported that there were no unusual weather conditions and the fields were not exposed to flooding during the growing or harvesting period. According to Mr. Andrus, manure and compost have not been applied to the ranch in more than 20 years and the field has never been subleased to another grower. Mr. Andrus had not noticed any wildlife on the Callaghan Ranch.

Andrus Farms owns all equipment used on the Callaghan Ranch for the cultivating of the crop (tractors, disks, blades, etc.). Farm equipment used for the Callaghan ranch is stored on the farm in a storage shed. The equipment is not leased to other growers and it is not cleaned or sanitized.

Pacific International Marketing (PIM), Salinas, California, a third party audit firm, tested the well water November 3, 2003 and reported the absence of total coliforms and *E. coli* (Attachment 86). The romaine crop was irrigated by sprinklers for the entire growing period. Water was pulled directly from the well to irrigate Callaghan 19-A.

21. Cassin Ranch-2

Contacts:

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(831) 758-1390

Investigator Myers and Dr. Thomas conducted a farm investigation of Cassin Ranch on November 5, 2003. Mr. Snow and Mr. Dobler were present during the investigation. Cassin Ranch is located east of Hwy 101 San Juan Road, Aromas, California. The Cassin Ranch is divided into two 34-acre fields (Attachment 87). Dobler & Sons, LLC grew romaine on Cassin Ranch-2 and RR harvested approximately two acres of the field. Cassin Ranch-2 was planted with romaine seeds on July 12, 2003, and harvested by RR on September 17, 2003. Because of the harvest date, Cassin Ranch-2 was identified by CDHS-FDB as a high probability farm.

Dobler and Sons employs approximately six workers on the Cassin Ranch. The employees are primarily responsible for soil preparation, planting, and irrigating. According to Mr. Dobler, no employees were ill during the 2003 season. However, no employee records were provided to the ERU staff.

One well supplied water to the ranch. Sprinklers were used on the romaine crop for the entire growing period. The well was properly sealed with its base on a cement pad. Test results in May 2003 by Soil Control Lab (Salinas, California) showed a “present” (no count provided) of coliforms (Attachment 88). On December 15, 2003 ERU staff submitted two liters of Cassin Ranch well water to the CDHS-FDB-Richmond Laboratory for coliform testing. The test results showed less than two MPN/100 ml for total coliform, fecal coliform, and *E. coli* (Attachment 60).

Cassin Ranch is bordered by a road on one side and farmland on the other three sides. The Pajaro River is approximately one-eighth of a mile to the north. According to Mr. Dobler, fox, deer, and coyote had been observed on the ranch. ERU staff observed dogs in the immediate area.

Dobler & Sons, LLC own all of the equipment used on the farm for cultivating (tractors, disks, blades, etc.). The equipment, which is shared with other Dobler & Sons ranches, is stored at Dobler’s main ranch off of Hwy 129. The equipment is hosed off if muddy and pressure washed once a year with a soap solution.

Dobler & Sons, LLC alternate the lease of Cassin Ranch every other year with Royal Oaks Farms, strawberry growers. Royal Oaks Farms applies compost supplied by T & L Trucking, Watsonville, California. Mr. Gary Wagaman, Farm Manager at Royal Oaks Farms stated that the compost is green waste. Mr. Wagaman stated that to his knowledge there is no animal

manure incorporated into the compost. After applying the green compost and before planting, the strawberry field is fumigated with methyl bromide chloropicrin.

22. Lukrich Ranch-2

Contacts:

Craig Dobler, Partner
174 Struve Road, Moss Landing, California 95039
(831) 801-0004

Brian Snow, Growers Relations, River Ranch Fresh Foods, LLC
1085 Abbott Street, Salinas, California, 93901
(831) 758-1390

On November 5, 2003, Investigator Myers and Dr. Thomas conducted a farm investigation at Lukrich Ranch-2. Mr. Snow was present during the investigation of Lukrich Ranch-2. The ranch is divided into two fields with Field 2 equaling 40 acres (Attachment 89). Lukrich Ranch-2 was planted with romaine seed on July 19, 2003, and harvested by RR on September 9, 2003. Because of the September 9, 2003, harvest date, Lukrich Ranch-2 was identified by CDHS-FDB as a low probability farm. Although Mr. Dobler was not present when Mr. Snow and ERU staff visited Lukrich Ranch, he gave the following information on November 5, 2003 when ERU staff interviewed him at the Cassin Ranch.

Dobler & Sons, LLC has two employees responsible for soil preparation, planting, and irrigating Lukrich Ranch-2. Dobler & Sons have a thinning crew of about 20 people, however, contract labor is sometimes used. Mr. Dobler stated that no employees reported being ill during the fall of 2003. However, no employee records were provided to the ERU staff. AJAX Portables supply toilet and handwashing facilities to the workers.

Mr. Dobler reported that no animal manure, compost, or biosolids were used to amend the soil on Lukrich Ranch-2. Heavy winds were present during 2003, but the lettuce crop was not damaged. There were no other unusual weather conditions or flooding during the growing or harvesting period. Mr. Dobler reported that there has never been animal damage to the field and wildlife had not been observed in the field.

Dobler & Sons, LLC alternate the lease of Lukrich Ranch-2 approximately every third year with Ortega Berries Farms, strawberry growers. Mr. Ed Ortega stated that he has never used compost of any type nor animal manure on the Lukrich Ranch-2. Mr. Ortega fumigates the field with methyl bromide before Dobler & Sons, LLC begin soil preparation.

Dobler & Sons, LLC own all of the equipment used on the farm for cultivating (tractors, disks, blades, etc.). The equipment, which is shared with other Dobler & Sons ranches, is stored at Dobler's main ranch off of Hwy 129. The equipment is hosed off if muddy and pressure washed once a year with a soap solution.

The romaine crop was irrigated by overhead sprinklers from water supplied by the Lukrich well. On May 27, 2003 Soil Control Lab (Watsonville, California) tested the Lukrich well. The test results were negative for total coliforms and *E. coli* (Attachment 90).

Pismo Oceano Vegetable Exchange (POVE)

23-24. Ikeda Ranch 27-01, 27-04

Contacts:

Vard Ikeda, Owner
P.O. Box 518, Oceano, California 93445
(805) 489-2526

Dan Sutton, Plant Manager - POVE
PO Box 368, Oceano, California 93445
(805) 473-4930

On November 4, 2003, Dr. Thomas conducted a farm investigation at Ikeda Ranch 27-01 and Ikeda Ranch 27-04. Mr. Ikeda and Mr. Sutton were present during the visit. The ranch is located east of Arroyo Grande, California. Ikeda Ranch 27-01 is sectioned into three separate fields (Attachment 91). Four and a half acres of romaine seedlings were planted on Ikeda Ranch 27-01 on July 21, 2003, and harvested by L & C (Guadalupe, California) September 5, 2003. The 16-acre Ikeda Ranch 27-04 was planted with romaine seedlings on July 29, 2003, and harvested on September 18, 2003. Because of the harvest date, Vard Ikeda's Ranch 27-04 was identified by CDHS-FDB as a high probability farm.

Mr. Ikeda employees 12 workers responsible for soil preparation, planting, irrigating, and thinning. There were no reported employee illnesses during the growing and harvesting of the romaine crop. However, no employee records were provided to the ERU staff. Handwashing facilities and toilets are provided to the employees when they are working on the Ikeda Ranch. Toilet facilities were noted on the day of the visit and were supplied with soap, water, and paper towels.

Mr. Ikeda reported that no animal manure, compost, or biosolids were used to amend the soil of Ikeda Ranch 27-04 and 27-01. Green waste compost, produced by Community Recycle, was applied 2 weeks prior to the planting of the seedlings. Documentation provided by Community Recycle stated that no animal manure was added to the product (Attachment 92). Mr. Ikeda stated that he has not seen wildlife on the cultivated field, but has, on occasion, seen deer and coyote in the surrounding areas.

Mr. Ikeda uses POVE equipment for all of his farming activities. The equipment is used and maintained by the cooperative farms. The equipment is stored at Stan Ikeda's ranch and is washed and pressure washed as needed.

The field was irrigated using sprinkler irrigation methods after transplanting the seedlings. Furrow irrigation was used for the remainder of the growing period. Water was supplied to the

ranch by a well, which was tested September 23, 2003, by Primus Labs, Santa Maria, California. The test results were less than 1 MPN/100 ml for *E. coli* (Attachment 93).

25-27. Ikeda Ranch 17-P7, 17-P9, 17-P11

Contacts:

Stan Ikeda, Owner
P.O. Box 518, Oceano, California 93445
(805) 489-2526

Dan Sutton, Plant Manager – POVE
PO Box 368, Oceano, California 93445
(805) 473-4930

On November 4, 2003, Dr. Thomas conducted a farm investigation of Ikeda Ranch 17. Mr. Ikeda and Mr. Sutton were present during the investigation. The ranch is located west of Oceano, CA. Ikeda Ranch 17 is located in Oceano, California and is divided into 18 fields (Attachment 94). The Ikeda Ranch 17-P7 romaine crop was planted with romaine seedlings on July 7, 2003, and harvested by L & C on September 8, 2003, and September 9, 2003. The Ikeda Ranch 17-P9 and Ranch 17-P11 were planted on August 4, 2003, and June 23, 2003, respectively and harvested September 29, 2003, and July 1, 2003, respectively. Because of the harvest date, the Stan Ikeda Ranch 17 was determined by DHS-FDB as a low probability farm.

Mr. Ikeda employs 12 workers who are responsible for soil preparation, planting, irrigating, and thinning. According to Mr. Ikeda, there were no reported employee illnesses during the growing and harvesting of the romaine crop. However, no employee records were provided to the ERU staff.

Mr. Ikeda reported that no animal manure, compost, or biosolids were used to amend the soil. Green waste compost produced by Community Recycle was applied to Ranch 17 (Attachment 92). Mr. Ikeda stated that he has not seen wildlife on the cultivated field, but has observed an occasional coyote in the area.

Water is supplied to the ranch by a well, Pump #11, which was tested September 23, 2003 by Primus Labs, Santa Maria, California. The test results were 3.1 MPN/100 ml total coliform and less than 1 MPN/100 ml for *E. coli* (Attachment 95). The romaine crop was first irrigated by overhead sprinklers and then furrow irrigated until harvesting.

28. Dohi Ranch 8 P-81

Contacts:

Hugh Dohi, Owner
310 Fair Oaks Ave, Arroyo Grande, California 93420
(805) 489-2929

Dan Sutton, Plant Manager – POVE
PO Box 368, Oceano, California 93445
(805) 473-4930

On November 4, 2003, Dr. Thomas conducted a farm investigation of Dohi Ranch 8 P-81. Mr. Dohi and Mr. Sutton were present during the investigation. Dohi Ranch 8 is divided into five fields and is located east of San Luis Obispo, California (Attachment 96). Four acres of the Dohi Ranch 8 P-81 field were planted with romaine seedlings on August 14, 2003, and harvested on September 22, 2003, by Castaneva Farms (Grover Beach, California). Because of the September 22, 2003, harvest date, the Dohi Ranch was determined by CDHS-FDB as a high probability farm.

Mr. Dohi employs four to five workers who are responsible for soil preparation, planting, irrigating, and thinning. There were no reported employee illnesses during the growing and harvesting of the romaine crop. However, no employee records were provided to the ERU staff. According to Mr. Dohi, toilet and handwashing facilities are provided when employees are working on the ranch.

Mr. Dohi reported that no animal manure, compost, or biosolids were used to amend the soil. There were no unusual weather conditions and the fields were not exposed to flooding during the growing or harvesting period. Mr. Dohi reported that some deer and coyotes move through the area on a regular basis. There was a small feedlot (12 cows) noted approximately two miles southeast of the field. Dohi Ranch owns all the equipment used on the farm for the cultivating of the crop (tractors, disks, blades, etc.)

The romaine crop was watered with drip irrigation. Water is supplied to the ranch by a well, which was tested September 11, 2003 by Primus Labs, Santa Maria, California. The test results were 22.2 MPN/100 ml total coliform and less than 1 MPN/100 ml for *E. coli* (Attachment 97).

29. Arroyo Fresh – Ranch 4 P-41

Contacts:

Pablo Valdez, Farm Manager
5120 Louma Lane, Arroyo Grande, California 93420
(805) 489-1602s

Leroy Saruwatari, Owner
5120 Louma Lane, Arroyo Grande, California 93420
(805) 431- 0523

Dan Sutton, Plant Manager – POVE
PO Box 368, Oceano, California 93445
(805) 473-4930

On November 4, 2003, Dr. Thomas conducted a farm investigation of Arroyo Fresh, Inc., Ranch 4 P-41. Mr. Valdez and Mr. Sutton were present during the investigation. Ranch 4 is divided into three fields and is located in Arroyo Grande, California (Attachment 98). The 15-acre Ranch 4 P-41 was harvested for romaine on October 3, 2003, by Castaneva Farms (Guadalupe, California). The field was planted with spinach at the time of this investigation. Because of the late harvest date, the Arroyo Fresh Ranch was determined by CDHS-FDB as a low probability farm.

Arroyo Fresh employs 20 workers who are responsible for soil preparation, planting, irrigating, and thinning. According to Mr. Valdez, there were no reported employee illnesses during the growing and harvesting of the romaine crop. However, no employee records were provided to the ERU staff. Toilet and handwashing facilities are provided to employees when they are working on the ranch.

Mr. Valdez reported that no animal manure, compost, or biosolids were used to amend the soil. Mr. Valdez stated that he has not seen wildlife on the cultivated field. There were no unusual weather conditions and the fields were not exposed to flooding during the growing or harvesting period. Residential housing, farms, and roads border the farm. All homes surrounding this field are on a city sewage system.

Arroyo Fresh owns all the equipment used on the farm for the cultivating of the crop (tractors, disks, blades, etc.) The equipment is not leased to other growers and is cleaned by a water wash and steam cleaned as needed.

Water is supplied to the ranch by a well, pump P-32, which was tested September 3, 2003 by Primus Labs, Santa Maria, California. The test results were less than 1 MPN/100 ml for both total coliform and *E. coli* (Attachment 99).

POVE Harvesting

ERU staff observed POVE harvesting at Stan Ikeda's ranch on November 4, 2003. This was the only POVE harvest that was available for observation during the time of the investigation. L & C harvesting crew (Guadalupe, California) was contracted to cut the romaine plants in the field. L & C used Ikeda's Brothers' equipment for the romaine harvesting. Typically a harvest crew consisted of approximately 10-15 individuals.

The harvesting tool used by L & C had a stainless steel blade at one end with a plastic handle and a coring blade at the opposite end. An employee, using the harvesting tool, cut the romaine from the stem and placed the romaine head on the harvesting table. The lettuce was then picked up by an employee and transferred to a plastic-lined cardboard bin sitting on a truck. Attachment 100A-E show photographs of the POVE romaine lettuce harvesting. The harvest table was a food grade surface, however; on the day of the visit the table was covered with cardboard (Attachment 100B).

The harvest tools were not cleaned on a regular basis and were stored at the workers' home each night. It was optional for the harvesting crew to wear gloves, protective sleeves, or aprons.

Portable toilets and handwashing facilities were available to employees on the day of the visit. The toilets were clean and readily available to the harvesting crew. A handwashing station was located with the portable toilets. Soap, water, and paper towels were noted at this station.

On November 23, 2003, ERU staff collected eight environmental samples from the harvest table used by the POVE cooperative farms. The samples were collected aseptically using Solar Biologicals, Inc. (Lot # AL 03-5025, Exp. May 1, 2005) sponges with buffered peptone water. With pressure, the sponges were rubbed over the collection area, approximately a six inch square. All samples were stored and transported in an ice chest with blue ice and delivered to CDHS-FDB-Richmond Laboratory. All samples were negative for *E. coli* (Attachment 101).

POVE Cooling:

On November 4, 2003, Dr. Thomas visited the POVE cooling facility, Pismo West Cooling Company, 1731 Railroad Avenue, Oceano, California. The POVE facility contained a hydrovacuum and a cold storage room with loading docks. The romaine lettuce was cooled for approximately 30-45 minutes. The hydrovacuum was found to be clean with no lettuce or other organic debris present (Attachment 102A-B).

Mr. Sutton stated that calcium hypochlorite tablets were added to the tube. This was accomplished by adding tablets to two floating containers located at opposite ends of the reservoir. The firm tested the chlorine levels in the reservoir water with an ORP meter. ORP calibration logs and ORP measurements from Pismo West Cooling Company are included with Attachment 14. On the day of the visit ERU staff measured the ORP level of the reservoir to be 785mV using an ORP meter (Double Junction Model/356050-02).

After the cooling cycle is completed, the pallets of lettuce are immediately transferred to the forced-air cold storage room. This room was found to be clean and orderly. All products were stored off of the floor on pallets.

Recommendations

Retail Outlets and Distribution Centers

1. Follow CDHS guidelines in "Reducing The Risk Of Foodborne Illness Associated With Green Onions And Other Produce – A Guide For The Retail Industry"
2. Retailers should require product distributors to document any changes or substitutes of product on invoices.
3. Use of raw manure on farms producing ready-to-eat produce poses a high risk. Produce buyers should ensure that growers do not use this practice.

Cooling Facilities

4. Sanitize and clean hydrovacuum reservoir water as frequently as needed and maintain logs to document these activities.

5. Sanitize and clean the vacuum (dry and/or wet) tube as frequently as needed and maintain logs to document these activities.
6. When using chlorine as a sanitizer, measure and record the free chlorine or ORP level of the reservoir water before each load.
7. Water used in hydrovacuums and hydrocoolers should be from a source that meets Title 22, California Code of Regulations drinking water standards. If water source is not from a municipal source, then water testing for total and fecal coliforms should be conducted on a biannual schedule. Recycled water should be monitored/treated to ensure that contaminants from previous loads are not introduced to subsequent loads.
8. Use of raw manure on farms producing ready-to-eat produce poses a high risk. Produce coolers should ensure that growers do not use this practice.

Cold Storage/Shipping Facilities

9. Written SOP's and SSOP's should be developed and readily available to staff that load and inspect incoming and outgoing trucks.
10. Staff should be trained and monitored in the appropriate use of SOP's and SSOP's.
11. Logs should be maintained for all truck inspections.

Processing Facilities

12. Adhere to GMPs and Sherman Food, Drug, and Cosmetic Laws that are applicable for processing conducted at the facility.
13. Processing firms must be registered with the California Department of Health Services.
14. Use of raw manure on farms producing ready-to-eat produce poses a high risk. Produce buyers and processors should ensure that growers do not use this practice.

Harvesting Practices

15. Clean and sanitize tools as frequently as needed.
16. Maintain cleaning logs for the cleaning and sanitizing of equipment.
17. Do not allow workers to take knives home; all knives should be stored in a clean and sanitary manner.
18. Knives are to remain in an appropriate sanitizer solution when not in use in the field and stored in a clean and dry environment overnight.
19. All water applied directly to the harvested product needs to be of an acceptable quality.

Farms

20. Develop/implement methods for discouraging large populations of wildlife in fields.
21. Where possible clean farm equipment before transferring from one ranch to another.
22. Do not allow equipment used for hauling raw or insufficiently composted manure onto ranches unless the equipment has been thoroughly cleaned and sanitized.
23. Only apply compost that has met Title 14, California Code of Regulations requirements.

24. Only purchase soil amendments (fertilizers, gypsum, compost) from companies that have procedures in place to prevent cross contamination of equipment and product from pathogen sources such as raw manure.
25. Request time and temperature documentation and results for required microbial testing (Title 14) for all composted material.
26. Use of raw manure on farms producing ready-to-eat foods poses a high risk. Produce buyers should ensure that growers do not use this practice.
27. Growers should be aware that irrigation water could potentially be a source of pathogens. The Good Agricultural Practices (GAPs) recommendations for water quality should be followed throughout the farming and harvesting processes.
28. Monitor the quality of irrigation water. The following references may be useful:
 1. Central Coast Regional Water Quality Control Board *Basic Plan* Chapter 3.
 2. Cooperative Extension, U. C. Davis *Good Agricultural Practices, A self-Audit, for Growers and Handlers*.
 3. EPA, *Implementation Guidance for Ambient Water Quality Criteria for Bacteria, May 2002 Draft*.
29. Know what amendments are used on fields when recently leased by another farmer and determine if amendments pose a pathogen threat to field crops.
30. Have well tested annually for total coliforms and fecal coliforms. Develop SOP's for treating well if necessary.
31. Prevent irrigation and agriculture/urban run-off ditches from flooding by having responsible agency/individuals maintain pumps and remove trash and excess silt from ditches.
32. Implement food safety training for all workers that come into contact with product.
33. Maintain all portable restrooms in accordance with the Good Agricultural Procedures (GAPs). The use of handwashing spigots with a "push knob" is not recommended because the use of such a device prevents proper handwashing.

Agencies

34. Continue research for possible product contamination sources and pathways of *E. coli* 0157:H7 at the farm level.
35. Local agencies should enforce codes/ordinances on discharges and run-off into drainage ditches where possible.

Contributing Factors

1. Contaminated food eaten raw.
2. Possible cross-contamination during processing, cooling, and growing:
 - Gold Coast Produce did not have SSOP's in place to prevent cross-contamination throughout the plant.
 - 3-D Cooling did not have SSOP's in place to prevent cross-contamination from the hydrovacuum reservoir water.

- 3-D Cooling did not have SOP's in place to prevent cross-contamination from well water source.
 - DP, RR, and POVE harvesting procedures did not have SSOP's in place to prevent cross-contamination from the workers' knives that comes into direct contact with the product.
 - Trucks were used to haul raw manure and finished compost with no cleaning or sanitizing between loads.
3. Possible toxic substances (petroleum products, pesticides, household products) and animal wastes likely added to Chinn Ranch 3 fields due to the flooding of the Santa Rita Creek.
 4. Contributing factors to the flooding of Santa Rita Creek likely included improper maintenance of the drainage ditch and of the pumping station.

Attachments

1. Traceback diagram (2 pages)
2. Invoices and bills of lading: RR to FTP (35 pages)
3. Invoices and Customer Product Summary of FTP deliveries to PO restaurants from September 15 – October 7, 2003
 - 3A: Invoices from PO restaurants with cases (159 pages)
 - 3B: Invoices from PO restaurants without cases (173 pages)
 - 3C: Customer Product Summary (8 pages)
4. Invoices: FTP to Baja Sonora Grill and Baja Sonora (11 pages)
5. 5A – Photo: GCP box and a bag of 70/30 lettuce mix
 5B – Photo: salad prep line at a PO's restaurant (1 page)
6. FTP invoices from GCP for September 15 – October 6, 2003 (60 pages)
7. FTP complete list of customers receiving lettuce product (35 pages)
8. FTP invoices and bills of lading for GCP 4-way-bite-size separated mix to schools and school districts (118 pages)
9. GCP customer sales list (4 pages)
10. GCP invoices to FTP from September 15 - October 6, 2003 (32 pages)
11. 11A - DP bills of lading for shipment from DP to GCP from September 2 - October 7, 2003 (18 pages)
 11B - DP invoices to GCP from September 8 - October 2, 2003 (14 pages)
 11C - DP bills of lading and field tags for romaine shipments from DP to GCP from September 2 - October 3, 2003 (27 pages)
12. DP list of iceberg lettuce growers (1 page)
13. RR Outside Sales Invoicing Request (bills of lading) (4 pages)
14. POVE invoices, bills of lading, and operator's daily logs for romaine shipments from September 1 – October 3, 2003 (53 pages)
15. San Diego County and Orange County Environmental Health Departments' inspectional reports for PO restaurants (18 pages)
16. PO ingredient list and preparation methods for salads (38 pages)
17. 17A – Photo: RR bagged chopped romaine
 17B – Photo: PO restaurant lunch salad preparations

- (1 page)
18. FTP account credits (6 pages)
 19. FTP Daily shipment records to PO from September 15 - October 6, 2003 (23 pages)

 20. 20A – Photo: FTP cold storage area
20B – Photo: FTP temperature gauge in cold storage area
(1 page)
 21. FTP “Storage Temperature Report” (1 page)
 22. FTP “Outbound Trailer Cleanliness Daily Report” (8 pages)
 23. CDHS-FDB “Investigation Report” for GCP (6 pages)
 24. CDHS-FDB “Report of Observation” for GCP (3 pages)
 25. FDA inspectional report for GCP (5 pages)
 26. Floor diagram of GCP (1 page)
 27. 27A – Photo: GCP raw ingredient storage
27B – Photo: GCP raw ingredient storage with forklift pathway
(1 page)
 28. 28A-B – Photos: GCP forklift runway (1 page)
 29. 29A – Photo: GCP Line #1 hopper and processing area
29B – Photo: GCP Line #1 trimming board
(1 page)
 30. 30A – Photo: GCP swirl bath
30B – Photo: GCP Line #1 reservoir #1
30C – Photo: GCP Line #1 plastic spin buckets
30D – Photo: GCP Line #1 reservoirs #1 and #2
(2 pages)
 31. 31A-B – Photos: GCP packaging red cabbage (1 page)
 32. 32A – Photo: GCP chlorine spray equipment
32B – Photo: GCP unsanitary plastic buckets
(1 page)
 33. 33A-B – Photo: GCP stacked plastic buckets (1 page)
 34. FDA Analyst Worksheets and Collection Reports for October 8, 2003 lettuce head samples (6 pages)
 35. 35A – Photo: GCP iodine hand dip
35B – Photo: GCP outside portable restrooms
(1 page)
 36. 36A-B – Photos: GCP foot dip (1 page)
 37. GCP quality control monitoring logs (56 pages)
 38. MSDS – Liquichlor/sodium hypochlorite 7-15% (8 pages)
 39. MSDS – Proprietary compound; descaler (2 pages)
 40. 40A-B – Photo: GCP vegetable cutting and preparation table (1 page)
 41. Photo – GCP unlabeled plastic jugs (1 page)
 42. 42A-B - Photos: GCP walls with black residue (1 page)
 43. FDA Analyst Worksheets and Collection Reports for GCP environmental samples, October 8, 2003 (12 pages)

44. CDHS-FDB Laboratory Analysis Request forms for GCP environmental samples, October 9, 2003 (6 pages)
45. CCHS-FDB Laboratory results for GCP environmental samples (1 page)
46. FDA Collection Reports for GCP one-pound bags of salad product, October 9, 2003 (10 pages)
47. FDA Analyst Worksheets for GCP one-pound bags of salad product, October 9, 2003 (5 pages)
48. FDA Analyst Worksheets and Collection Report for GCP ten bags of salad products, October 9, 2003 (3 pages)
49. 49A-B - Photos: GCP Line #2 (1 page)
50. GCP "Urgent Voluntary Recall" (1 pages)
51. CDHS-FDB "Record of Voluntary Condemnation and Destruction" (5 pages)
52. List of growers and farm information (1 page)
53. Farms and time frame spreadsheet (3 page)
54. Maps: Ocean Mist (2 pages)
55. MRWPCA Coliform Data (3 pages)
56. 56A-B – Photos: Sella Ranch resident geese (1 page)
57. FDA Report of Sample Analysis (2 pages)
58. Maps: Francioni Brothers – Wing Ranch (2 pages)
59. Well Analysis: Francioni Brothers ranches (1 page)
60. Microbial Diseases Laboratory Branch well water sample results (Tomasini Ranch, Wing 303C, Barrett 902B, Dobler-Cassin) (1 page)
61. Maps: Francioni Brothers – Hartnell 509 Ranch (2 pages)
62. Maps: Francioni Brothers – Barrett 902B Ranch (2 pages)
63. Maps: Bassetti Home 3 (2 pages)
64. Well Analysis: Neil Bassetti Farms (1 page)
65. Maps: Guidotti Brothers - Jim Ranch (2 pages)
66. Well Analysis: Guidotti Brothers- Jim Ranch (1 page)
67. Maps: Guidotti Brothers – Metz Ranch (2 pages)
68. Maps: Domingos Brothers – Tomasini Ranch (2 pages)
69. Maps: Huntington Farms – Pryor Ranch (2 pages)
70. Well Analysis: Huntington Farms - John Pryor Ranch (1 page)
71. Maps: Huntington Farms – Hilltown Ranch (2 pages)
72. Well Analysis: Huntington Farms - Hilltown Ranch (1 page)
73. Maps: Fabretti & Dedini - Home Ranch (2 pages)
74. Well Analysis: Fabretti & Dedini Ranch (1 page)
75. DP Food Safety Program (10 pages)
76. 76A-I Photos: DP Harvest (5 pages)
77. 77A – Photo: DP field equipment cleaning brushes
77B – Photo: DP portable restroom
(1 page)
78. 78A-C – Photos: 3-D Cooling facility (1 page)
79. 79A-C – Photos: Hydrovacuum/vacuum tubes at 3-D Cooling (2 pages)
80. Well Analysis: El Camino Water Company (4 pages)
81. Map: Comgro: Chinn Ranch 3 road map (1 page)
82. Map: Comgro: Chinn Ranch 3 field map (1 page)

83. Well Analysis: Chinn Ranch 3 (1 page)
84. Santa Rita Creek water sample analysis (1 page)
85. Maps: Andrus Farms - Callaghan Ranch (2 pages)
86. Well Analysis: Andrus Farms - Callaghan Ranch (1 page)
87. Maps: Dobler & Sons - Cassin Ranch (2 pages)
88. Well Analysis: Dobler & Sons - Cassin Ranch (1 page)
89. Maps: Dobler & Sons - Lukrich Ranch (2 pages)
90. Well Analysis: Dobler & Sons - Lukrich Ranch (1 page)
91. Maps: POVE - Ikeda 27-01, 27-04 (2 pages)
92. Community Recycle documentation (1 page)
93. Well Analysis: POVE - Ikeda Ranch 27 (1 page)
94. Maps: POVE - Ikeda Ranch 17 (2 pages)
95. Well Analysis: POVE - Ikeda Ranch 17 (1 page)
96. Maps: POVE - Dohi Ranch 8 (2 pages)
97. Well Analysis: POVE - Dohi Ranch 8 (1 page)
98. Maps: POVE - Arroyo Fresh Ranch 4 (2 pages)
99. Well Analysis: POVE - Arroyo Fresh Ranch 4 (1 page)
100. 100A-E - Photos: POVE harvest (3 pages)
101. Environmental sample results – POVE harvest equipment (1 page)
102. 102A-B – Photos: POVE cooling facility (1 page)